US009067074B2

(12) United States Patent
Polefko et al.

(10) **Patent No.: US 9,067,074 B2**

(45) **Date of Patent: *Jun. 30, 2015**

(54) **AUTOMATED SEARCH TO IDENTIFY A LOCATION FOR ELECTRICAL STIMULATION TO TREAT A PATIENT**

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(73) Assignee: **Greatbatch Ltd.**, Clarence, NY (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/937,463**

(22) Filed: **Jul. 9, 2013**

(65) **Prior Publication Data**

US 2013/0296972 A1 Nov. 7, 2013

Related U.S. Application Data

(63) Continuation of application No. 13/226,969, filed on Sep. 7, 2011, now Pat. No. 8,483,836.

(51) **Int. Cl.**

A61N 1/372 (2006.01)

A61N 1/36 (2006.01)

(52) **U.S. Cl.**

CPC ***A61N 1/37235*** (2013.01); ***A61N 1/36017*** (2013.01); ***A61N 1/36021*** (2013.01); ***A61N 1/36071*** (2013.01); ***A61N 1/36132*** (2013.01);

(Continued)

(58) **Field of Classification Search**

CPC A61N 1/37235; A61N 1/37247; A61N 1/36185; A61N 1/36021; A61N 1/36132; A61N 1/36071

USPC 607/46, 45, 59

See application file for complete search history.

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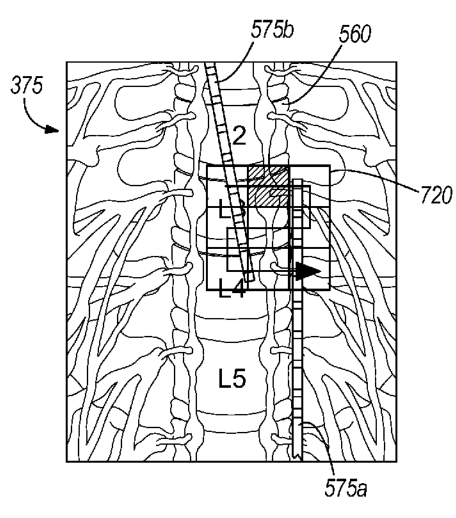
Primary Examiner — George Evanisko

(74) *Attorney, Agent, or Firm* — Michael Best & Friedrich LLP

(57) **ABSTRACT**

A stimulation system, such as a spinal cord stimulation (SCS) system, having an automated search to establish a program to treat a patient with electrical stimulation. The stimulation system includes an electrical stimulation generator, a medical lead coupled to the electrical stimulation generator, and a programmer with a communication interface, a display screen, and a user interface. The display screen displays an image of a spinal column and a position of the medical lead relative to the spinal column. The system includes an automated search that stimulates a series of regions and receives patient feedback via the user interface. The system then stimulates a series of subregions within a subset of the regions based on the feedback, receives additional feedback, and identifies a subset of the subregions location for stimulation based on the additional feedback.

19 Claims, 20 Drawing Sheets



(52) **U.S. Cl.**
CPC ***A61N 1/36185*** (2013.01); ***A61N 1/37247*** (2013.01)

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2012/0310305	A1	12/2012	Kaula	
2013/0060299	A1	3/2013	Polefko et al.	
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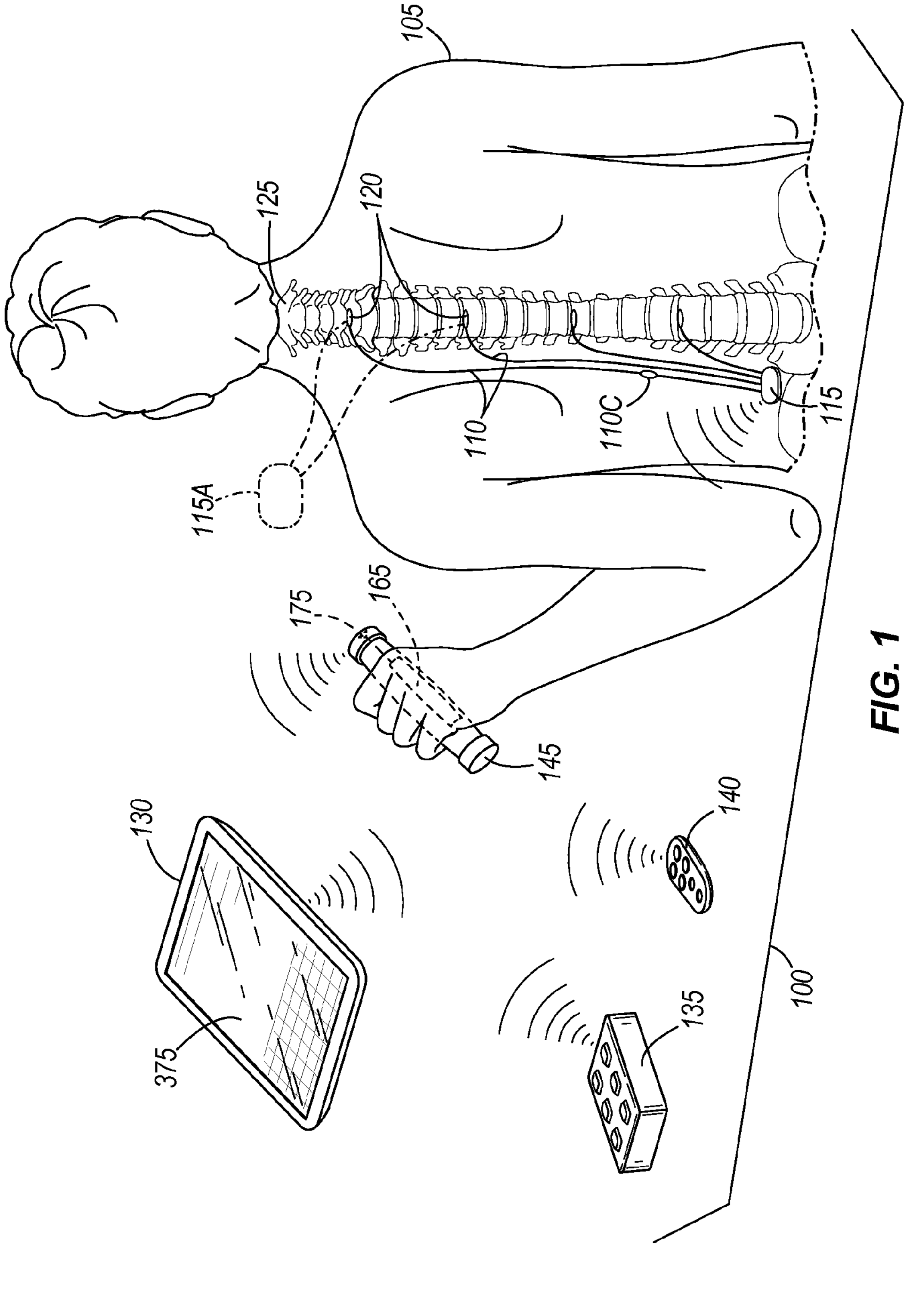


FIG. 1

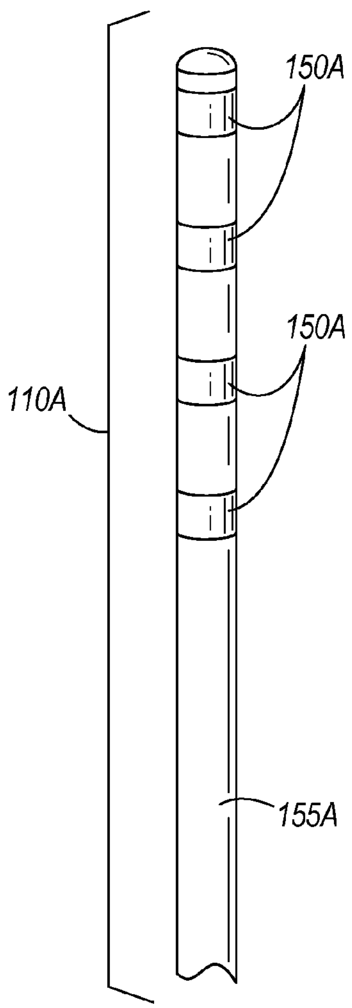


FIG. 2

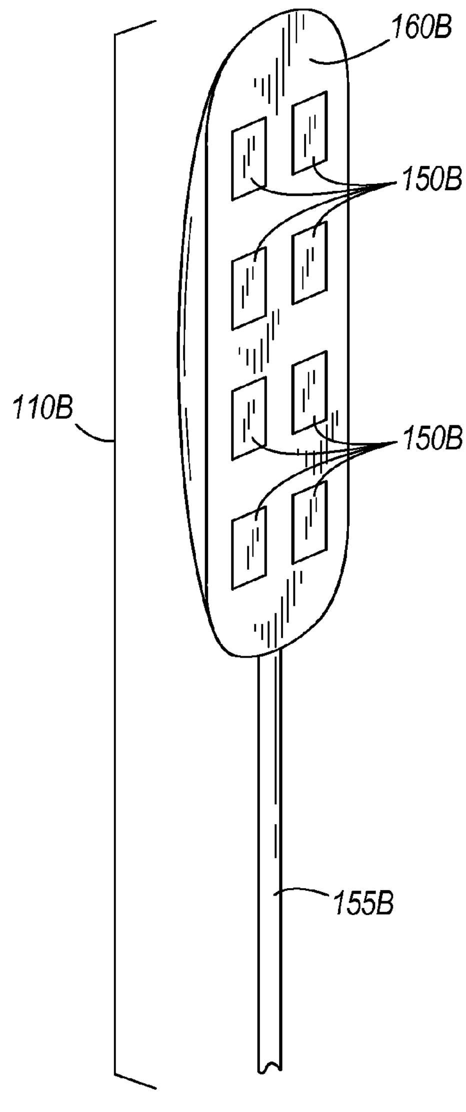
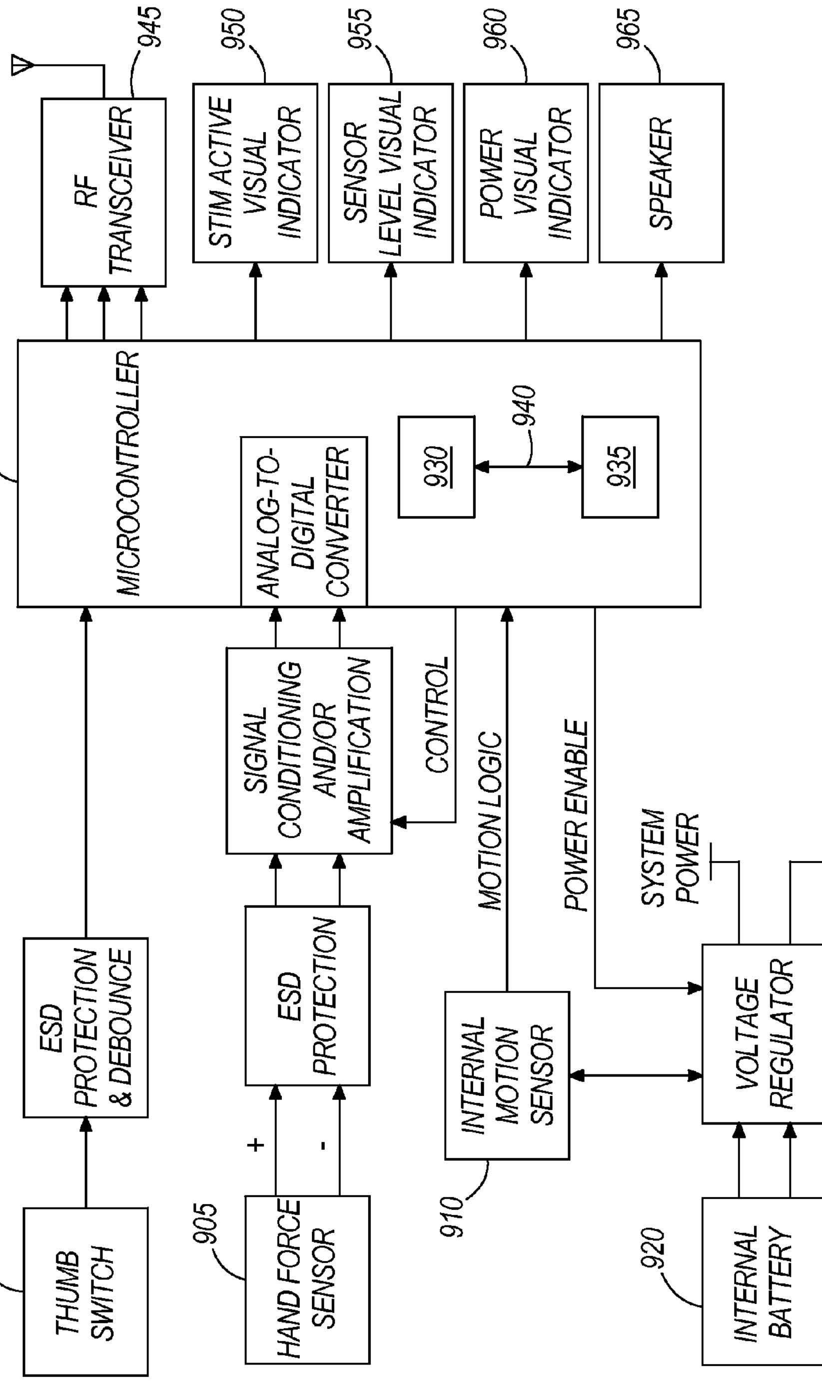


FIG. 3



THUMB SWITCH
900
ESD PROTECTION & DEBOUNCE
HAND FORCE SENSOR
905
+
-
ESD PROTECTION
SIGNAL CONDITIONING AND/OR AMPLIFICATION
CONTROL
INTERNAL MOTION SENSOR
910
MOTION LOGIC
POWER ENABLE
SYSTEM POWER
VOLTAGE REGULATOR
INTERNAL BATTERY
920
MICROCONTROLLER
925
ANALOG-TO-DIGITAL CONVERTER
930
935
940
RF TRANSCEIVER
945
STIM ACTIVE VISUAL INDICATOR
950
SENSOR LEVEL VISUAL INDICATOR
955
POWER VISUAL INDICATOR
960
SPEAKER
965

FIG. 4

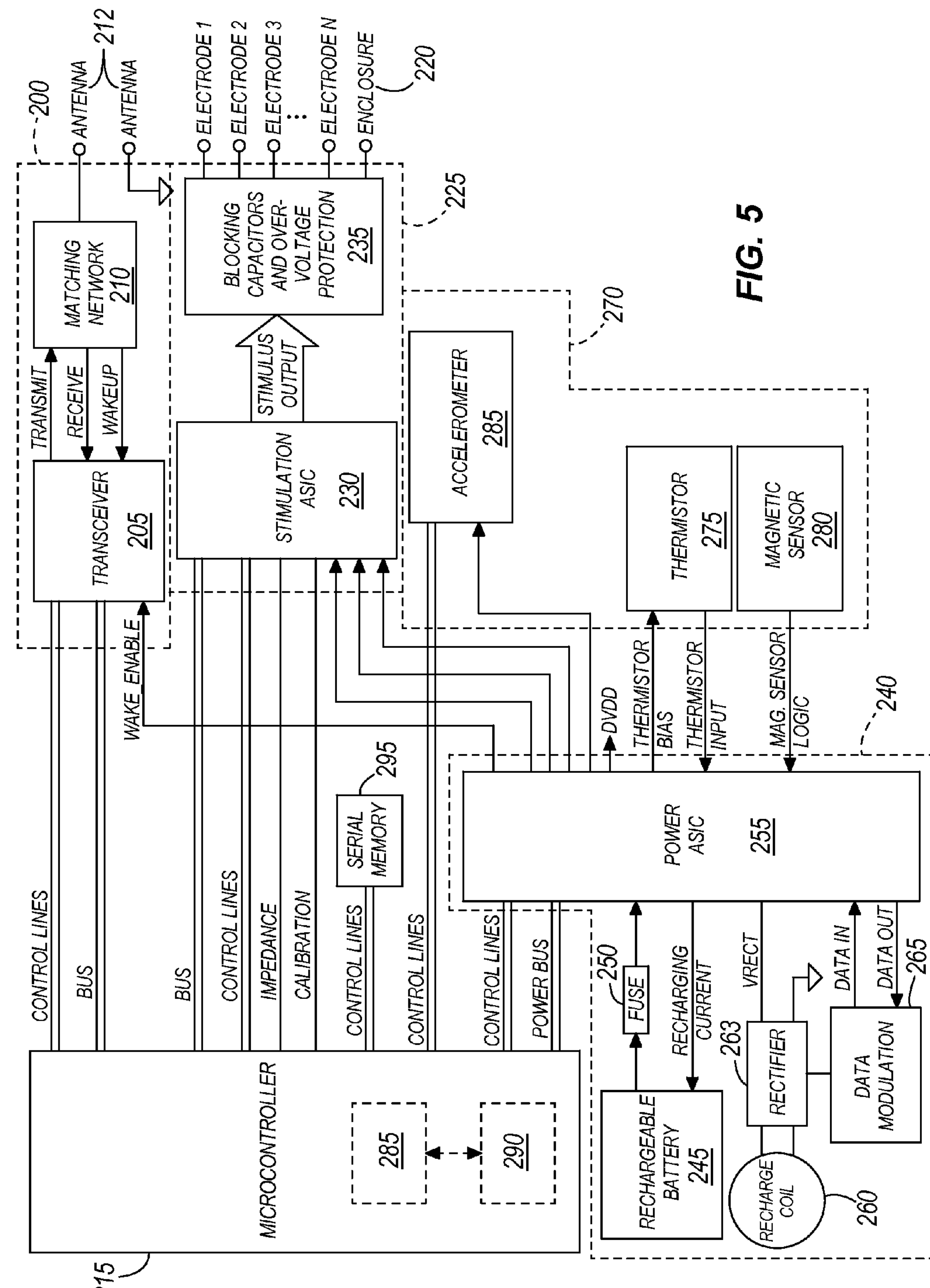

200
ANTENNA
ANTENNA
212
ELECTRODE 1
ELECTRODE 2
ELECTRODE 3
...
ELECTRODE N
ENCLOSURE
220
225
MATCHING NETWORK 210
BLOCKING CAPACITORS AND OVER-VOLTAGE PROTECTION 235
TRANSMIT
RECEIVE
WAKEUP
STIMULUS OUTPUT
270
TRANSCEIVER 205
STIMULATION ASIC 230
ACCELEROMETER 285
THERMISTOR 275
MAGNETIC SENSOR 280
WAKE ENABLE
DVDD
THERMISTOR BIAS
THERMISTOR INPUT
MAG. SENSOR LOGIC
240
295
SERIAL MEMORY
POWER ASIC 255
CONTROL LINES
BUS
BUS
CONTROL LINES
IMPEDANCE
CALIBRATION
CONTROL LINES
CONTROL LINES
CONTROL LINES
POWER BUS
250
FUSE
RECHARGING CURRENT
VRECT
DATA IN
DATA OUT
265
263
RECTIFIER
DATA MODULATION
MICROCONTROLLER
285
290
RECHARGEABLE BATTERY 245
RECHARGE COIL
260
215

FIG. 5

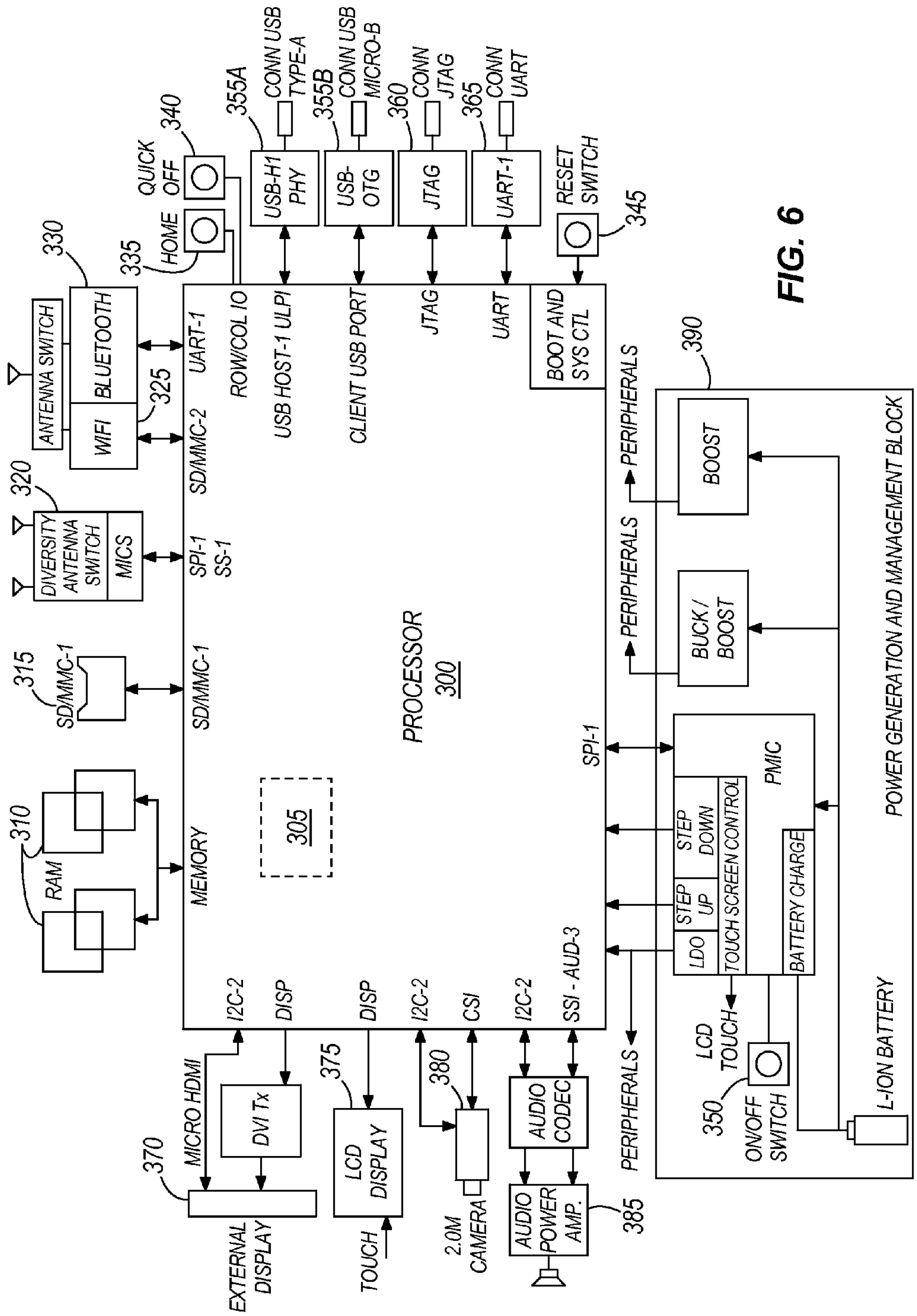
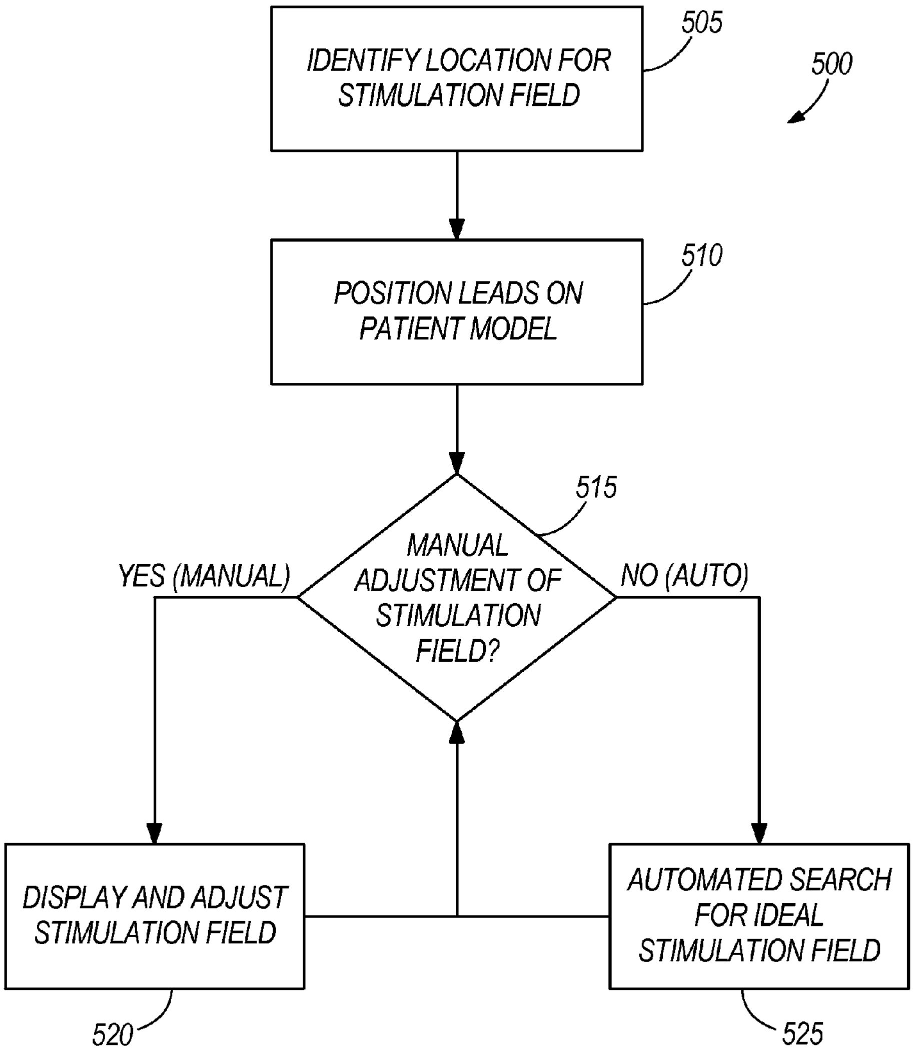

PROCESSOR
300
305
RAM
310
MEMORY
315
SD/MMC-1
320
DIVERSITY ANTENNA SWITCH
MICS
SPI-1
SS-1
325
WIFI
BLUETOOTH
ANTENNA SWITCH
330
SD/MMC-2
UART-1
335
HOME
340
QUICK OFF
ROW/COL IO
USB HOST-1 ULPI
CLIENT USB PORT
JTAG
UART
BOOT AND SYS CTL
355A
USB-H1 PHY
CONN USB TYPE-A
355B
USB-OTG
CONN USB MICRO-B
360
CONN JTAG
365
UART-1
CONN UART
RESET SWITCH
345
SPI-1
SSI - AUD-3
I2C-2
DISP
CSI
MICRO HDMI
DVI Tx
370
EXTERNAL DISPLAY
375
LCD DISPLAY
TOUCH
380
2.0M CAMERA
AUDIO CODEC
AUDIO POWER AMP.
385
PERIPHERALS
390
BOOST
BUCK / BOOST
PMIC
LDO
STEP UP
STEP DOWN
TOUCH SCREEN CONTROL
BATTERY CHARGE
LCD TOUCH
350
ON/OFF SWITCH
L-ION BATTERY
POWER GENERATION AND MANAGEMENT BLOCK

FIG. 6



IDENTIFY LOCATION FOR STIMULATION FIELD
505
500
POSITION LEADS ON PATIENT MODEL
510
MANUAL ADJUSTMENT OF STIMULATION FIELD?
515
YES (MANUAL)
NO (AUTO)
DISPLAY AND ADJUST STIMULATION FIELD
520
AUTOMATED SEARCH FOR IDEAL STIMULATION FIELD
525

FIG. 7

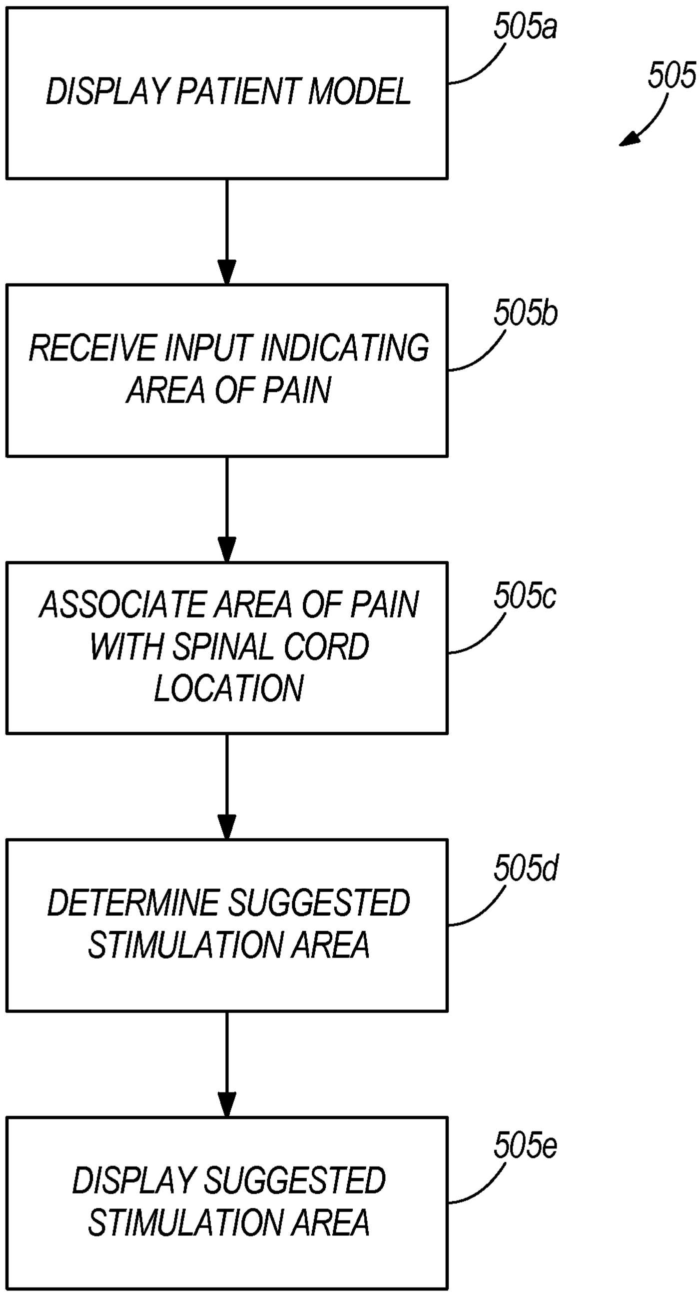

505
DISPLAY PATIENT MODEL
505a
RECEIVE INPUT INDICATING AREA OF PAIN
505b
ASSOCIATE AREA OF PAIN WITH SPINAL CORD LOCATION
505c
DETERMINE SUGGESTED STIMULATION AREA
505d
DISPLAY SUGGESTED STIMULATION AREA
505e

FIG. 8

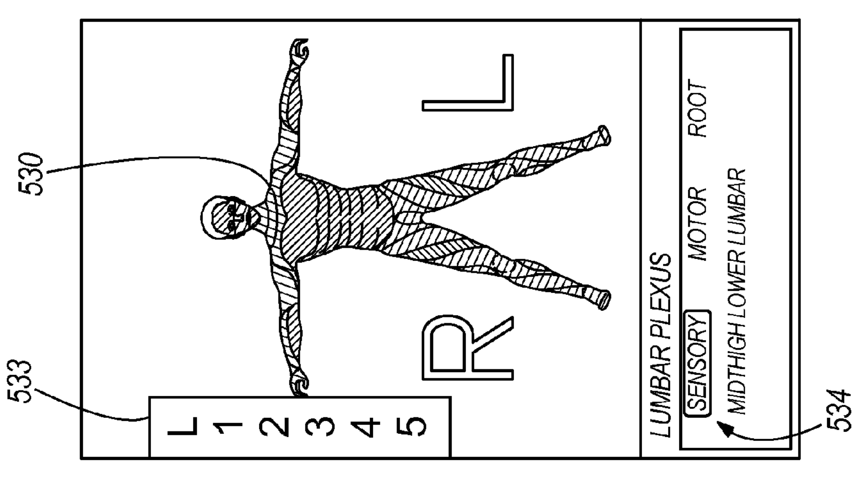


FIG. 9A

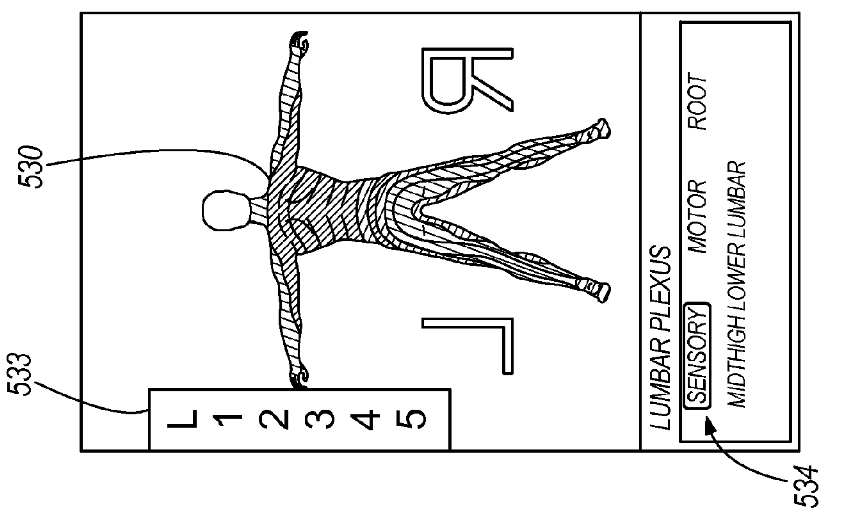


FIG. 9B

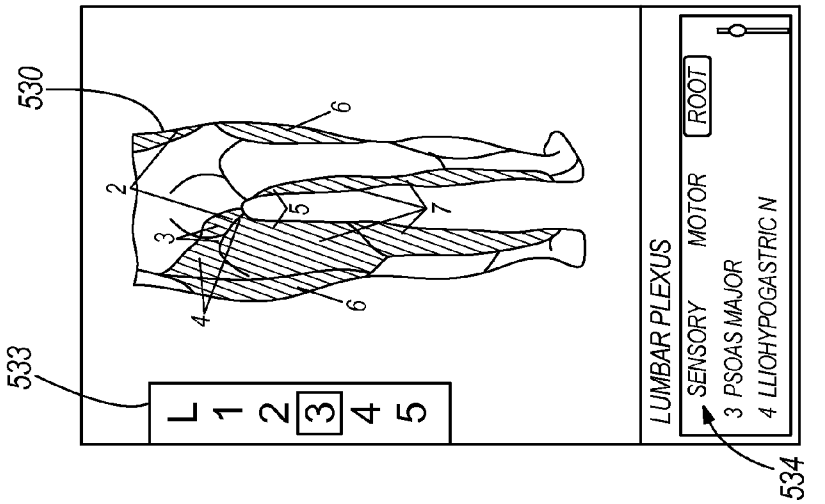


FIG. 9C

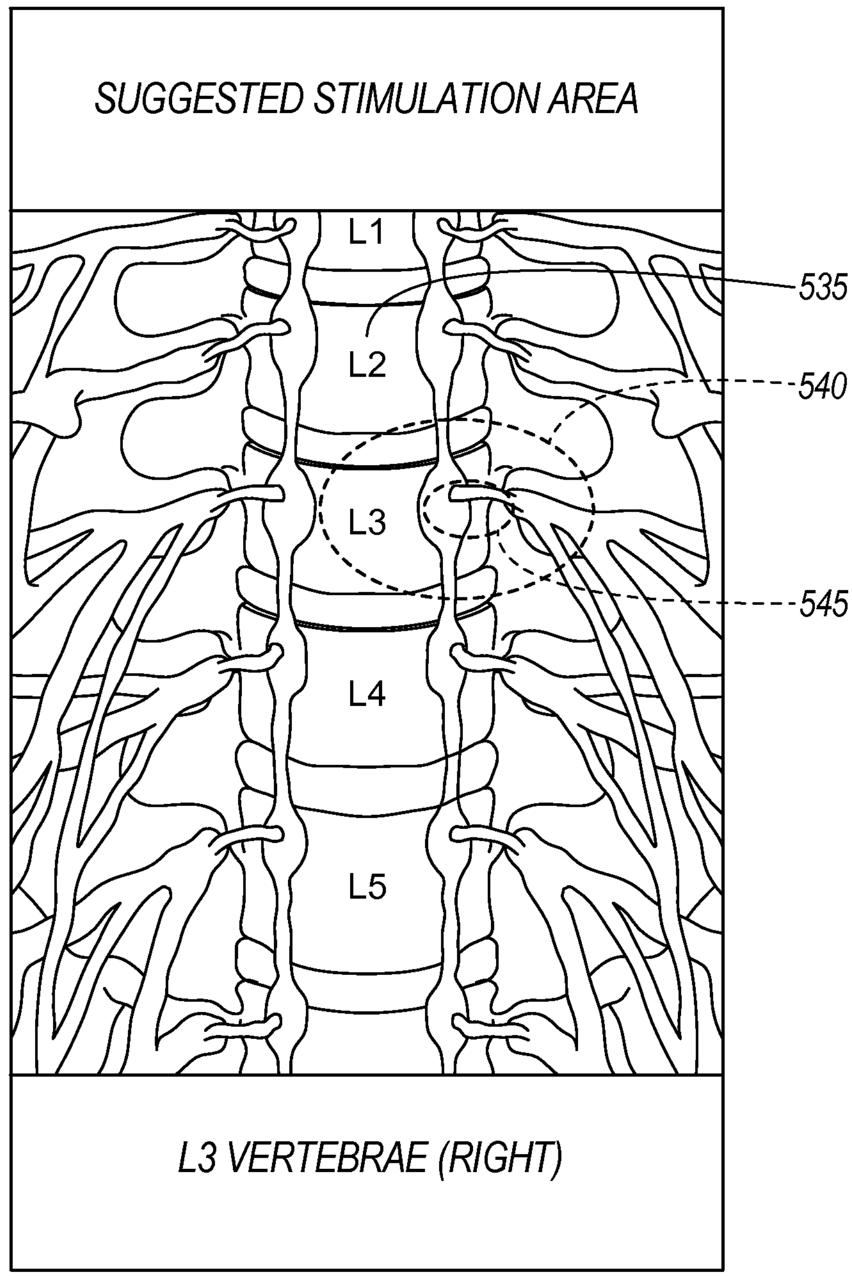

SUGGESTED STIMULATION AREA
L1
L2
L3
L4
L5
535
540
545
L3 VERTEBRAE (RIGHT)

FIG. 10

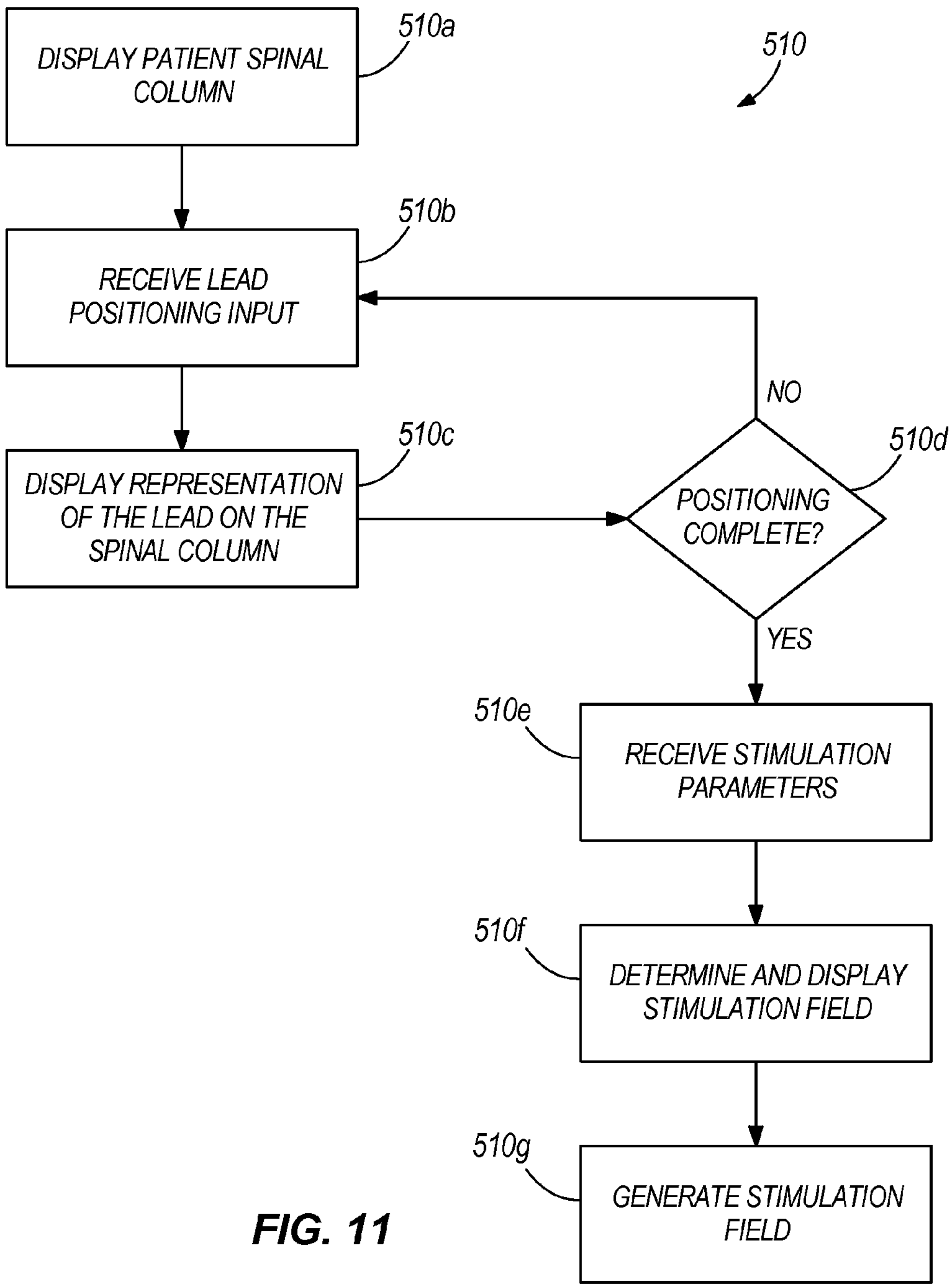

510
510a
DISPLAY PATIENT SPINAL COLUMN
510b
RECEIVE LEAD POSITIONING INPUT
510c
DISPLAY REPRESENTATION OF THE LEAD ON THE SPINAL COLUMN
NO
510d
POSITIONING COMPLETE?
YES
510e
RECEIVE STIMULATION PARAMETERS
510f
DETERMINE AND DISPLAY STIMULATION FIELD
510g
GENERATE STIMULATION FIELD

FIG. 11

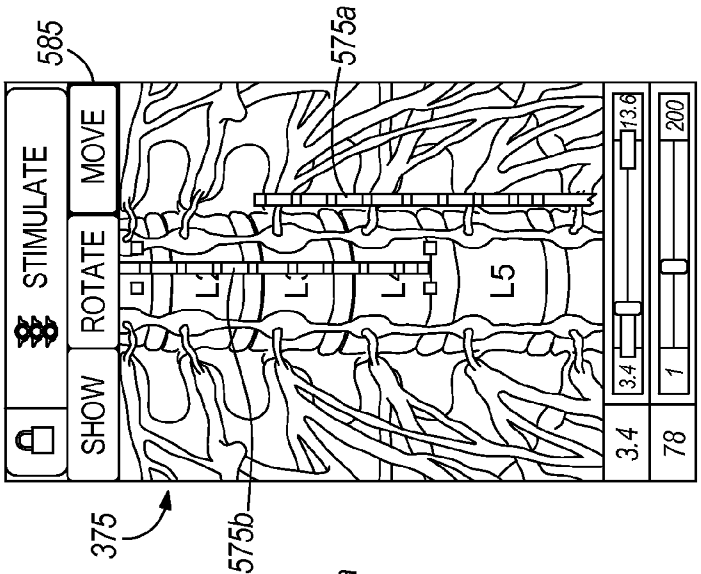


FIG. 12C

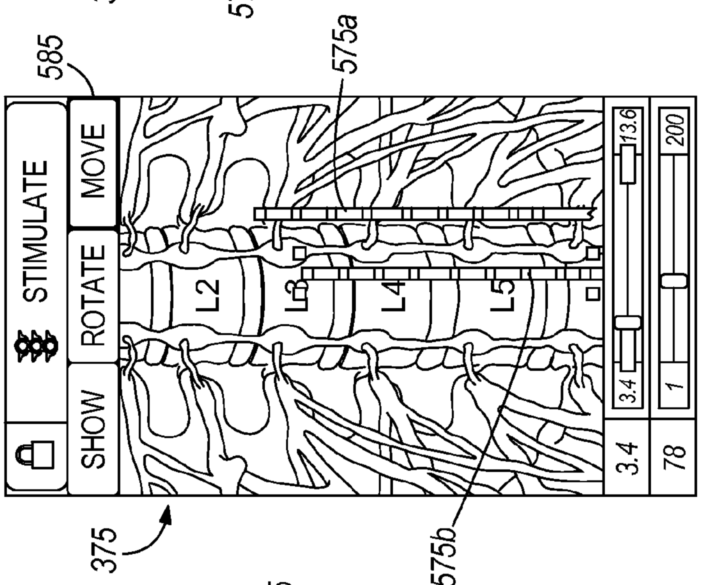


FIG. 12B

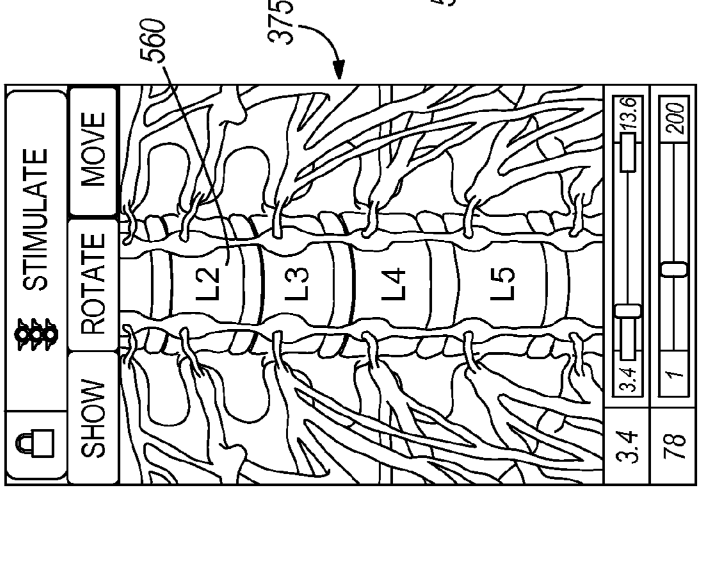


FIG. 12A

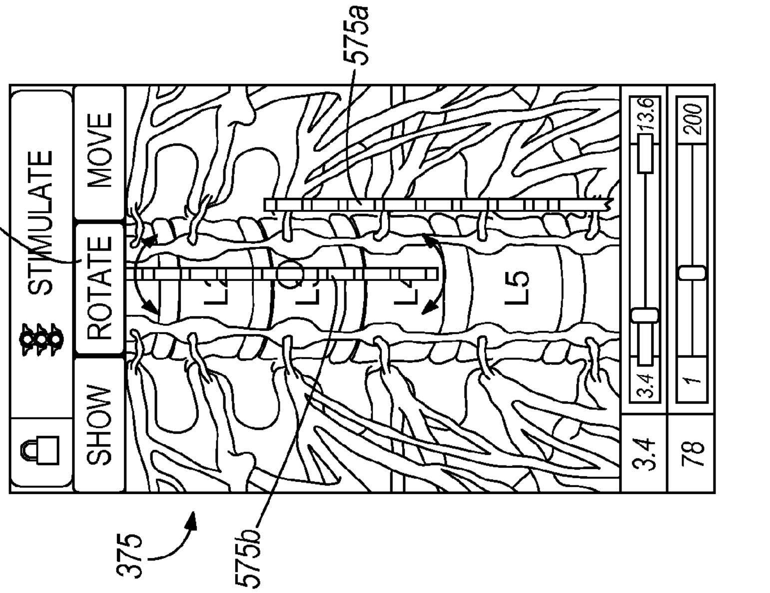


FIG. 12D

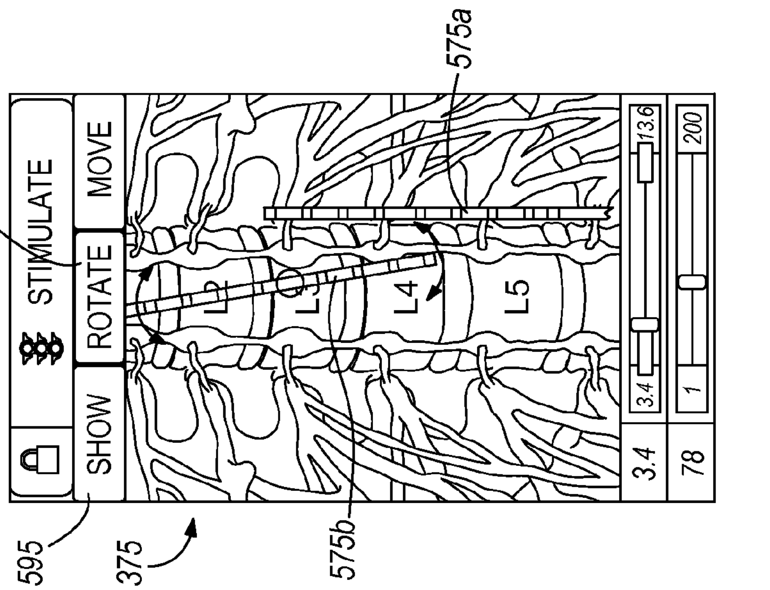


FIG. 12E

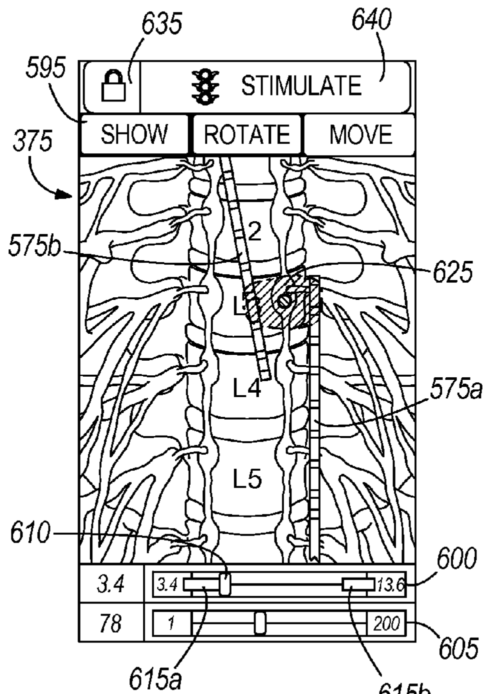


FIG. 12F

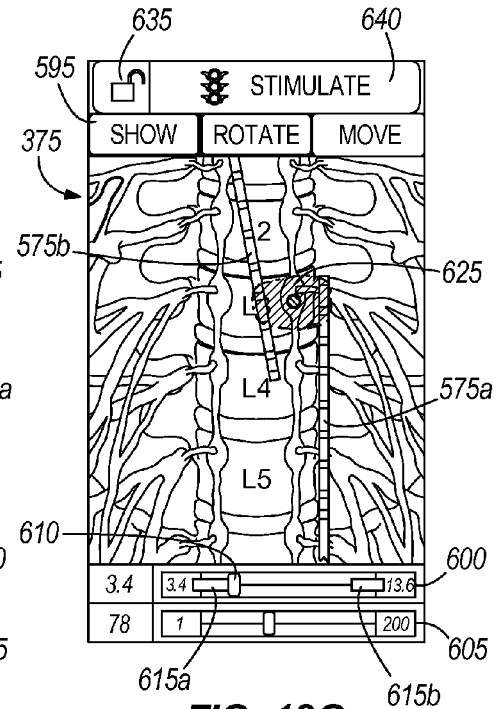


FIG. 12G

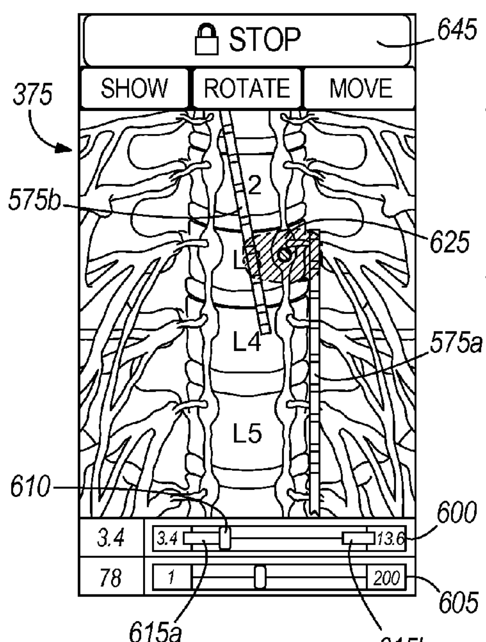


FIG. 12H

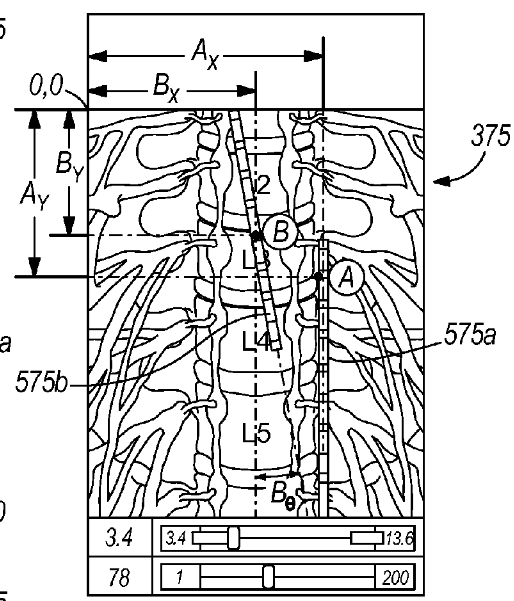


FIG. 12I

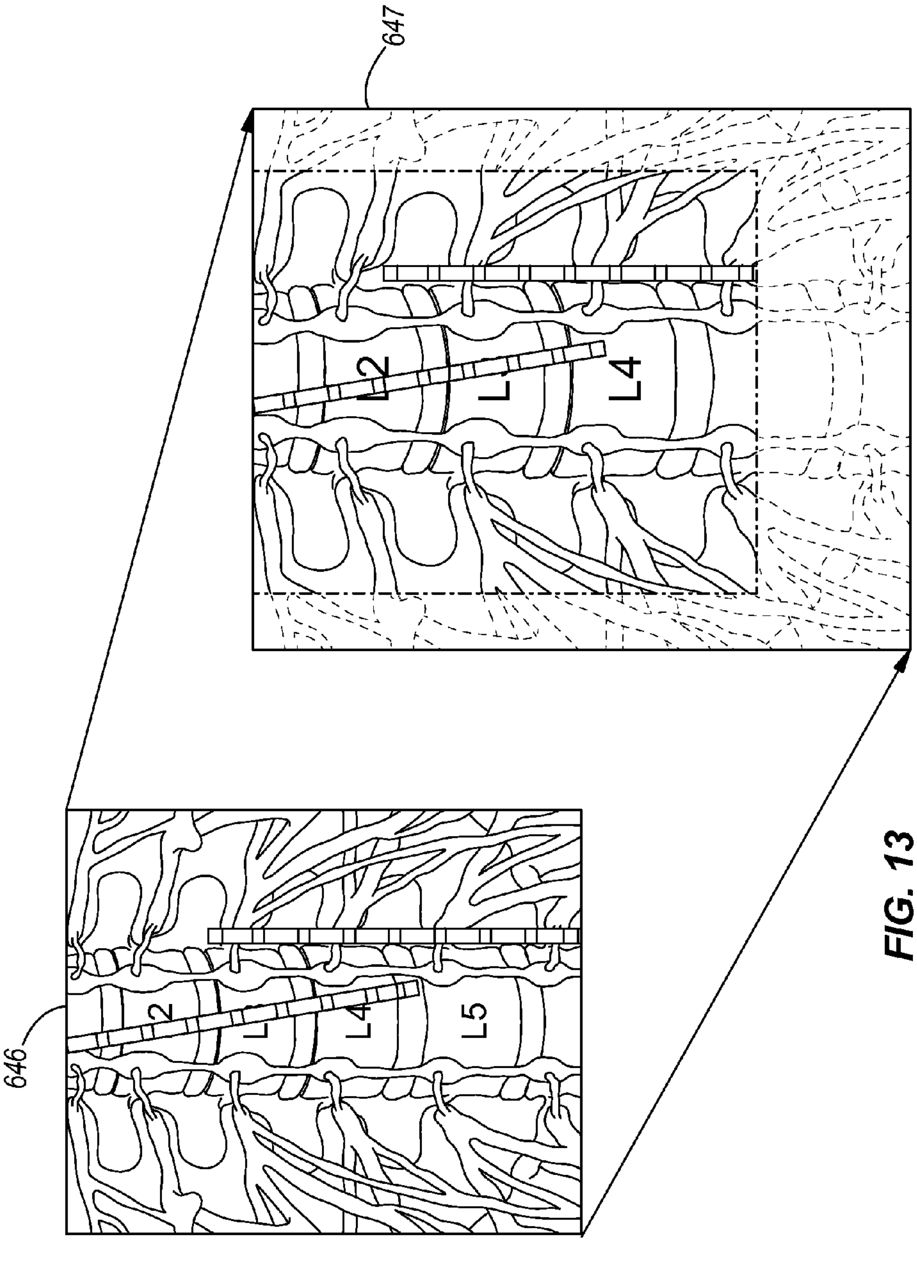


FIG. 13

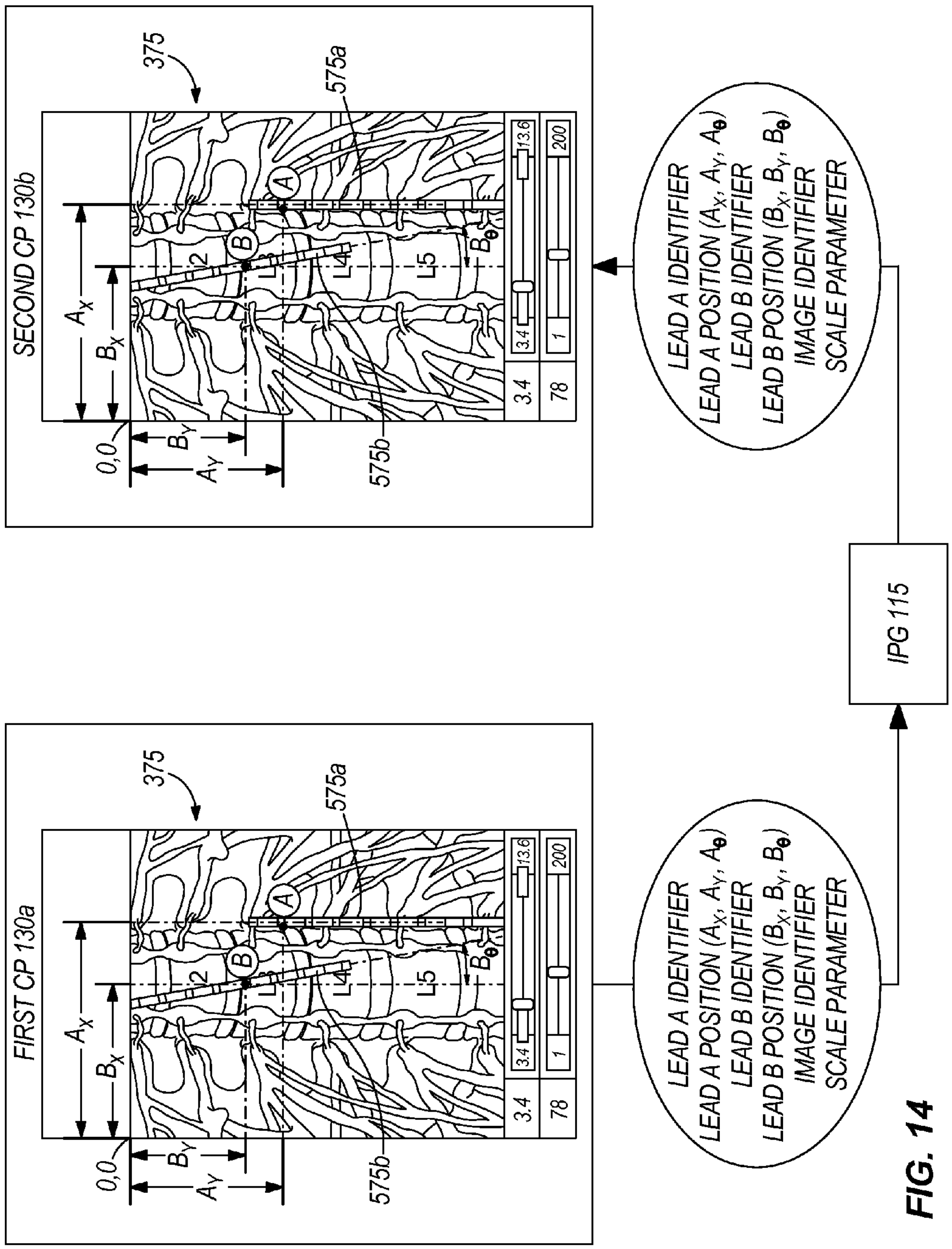
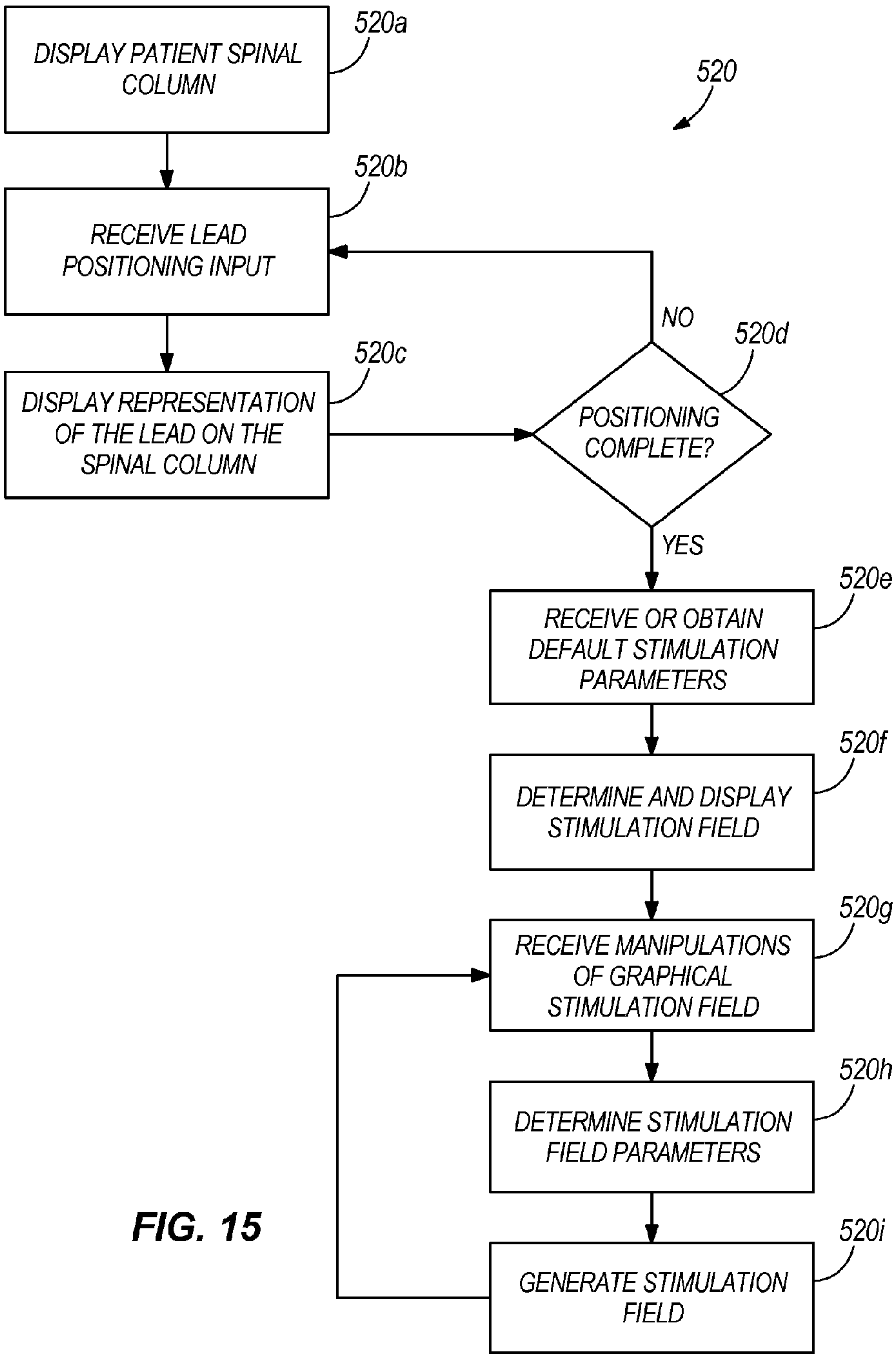

SECOND CP 130b
FIRST CP 130a
375
575a
575b
0,0
A_X
B_X
A_Y
B_Y
A
B
L2
L3
L4
L5
B_Θ
3.4
78
13.6
200
1
IPG 115
LEAD A IDENTIFIER
LEAD A POSITION (A_X, A_Y, A_Θ)
LEAD B IDENTIFIER
LEAD B POSITION (B_X, B_Y, B_Θ)
IMAGE IDENTIFIER
SCALE PARAMETER

FIG. 14



DISPLAY PATIENT SPINAL COLUMN
520a
520
RECEIVE LEAD POSITIONING INPUT
520b
DISPLAY REPRESENTATION OF THE LEAD ON THE SPINAL COLUMN
520c
NO
POSITIONING COMPLETE?
520d
YES
RECEIVE OR OBTAIN DEFAULT STIMULATION PARAMETERS
520e
DETERMINE AND DISPLAY STIMULATION FIELD
520f
RECEIVE MANIPULATIONS OF GRAPHICAL STIMULATION FIELD
520g
DETERMINE STIMULATION FIELD PARAMETERS
520h
GENERATE STIMULATION FIELD
520i

FIG. 15

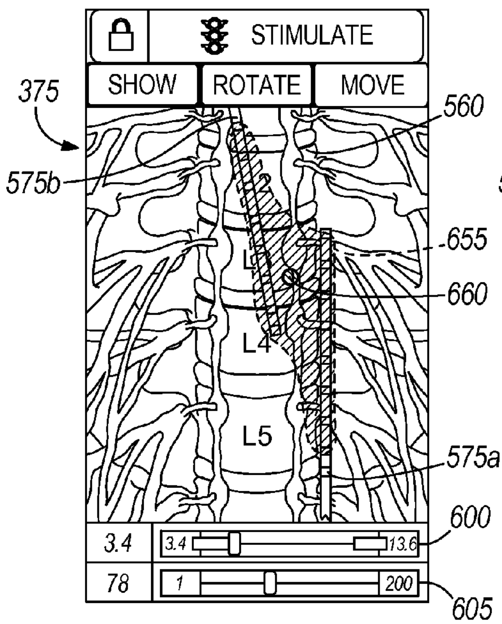


FIG. 16A

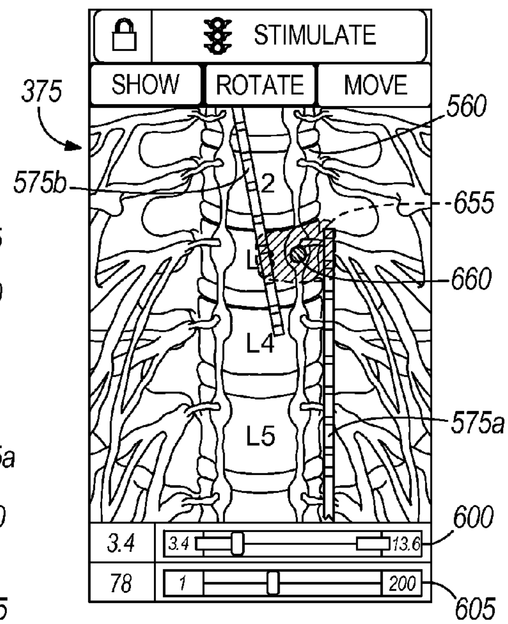


FIG. 16B

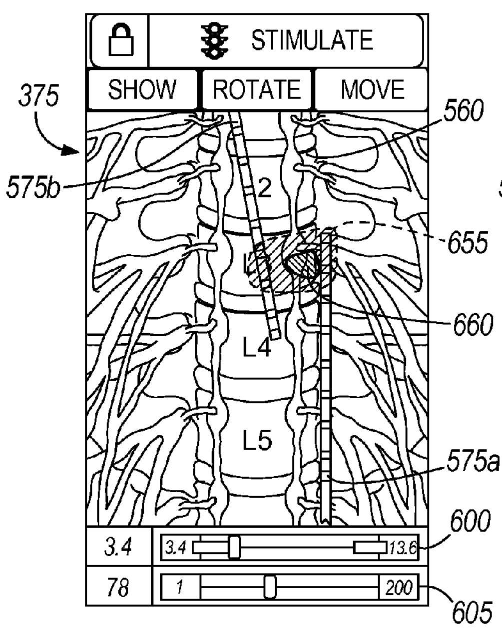


FIG. 16C

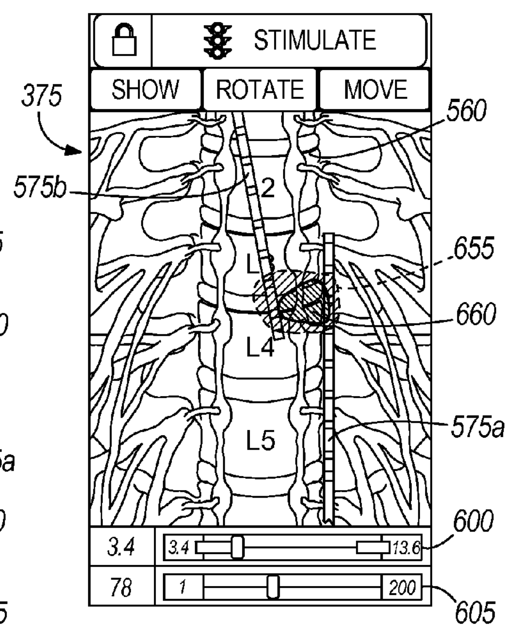


FIG. 16D

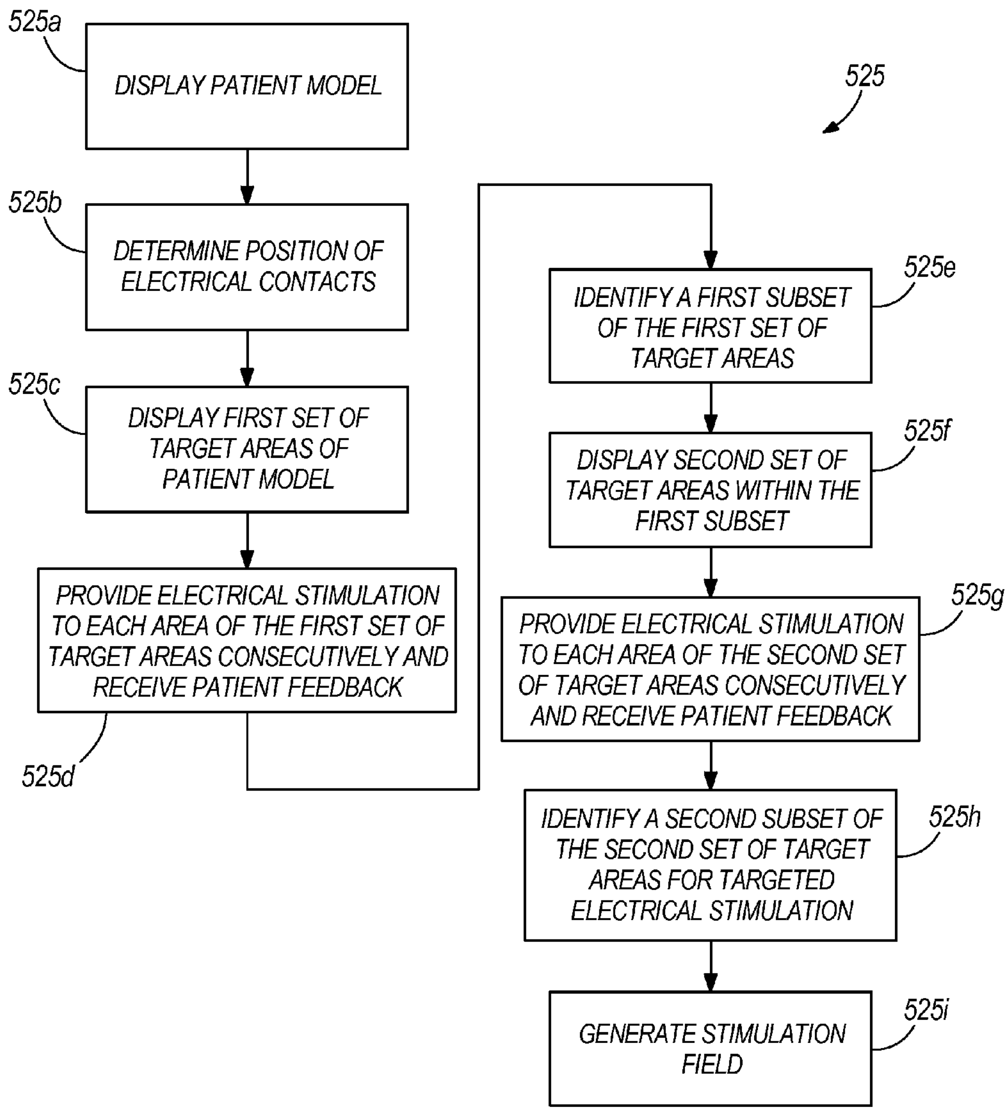

525a
DISPLAY PATIENT MODEL
525b
DETERMINE POSITION OF ELECTRICAL CONTACTS
525c
DISPLAY FIRST SET OF TARGET AREAS OF PATIENT MODEL
PROVIDE ELECTRICAL STIMULATION TO EACH AREA OF THE FIRST SET OF TARGET AREAS CONSECUTIVELY AND RECEIVE PATIENT FEEDBACK
525d
525
IDENTIFY A FIRST SUBSET OF THE FIRST SET OF TARGET AREAS
525e
DISPLAY SECOND SET OF TARGET AREAS WITHIN THE FIRST SUBSET
525f
PROVIDE ELECTRICAL STIMULATION TO EACH AREA OF THE SECOND SET OF TARGET AREAS CONSECUTIVELY AND RECEIVE PATIENT FEEDBACK
525g
IDENTIFY A SECOND SUBSET OF THE SECOND SET OF TARGET AREAS FOR TARGETED ELECTRICAL STIMULATION
525h
GENERATE STIMULATION FIELD
525i

FIG. 17

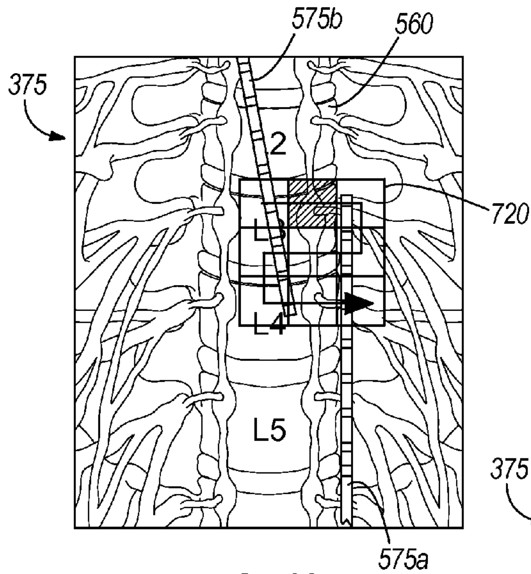


FIG. 18A

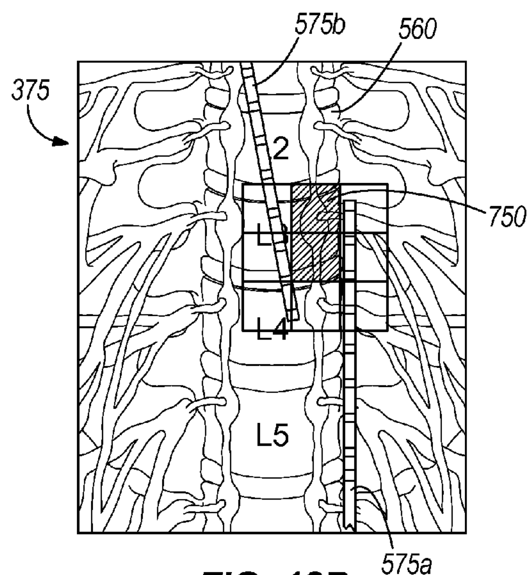


FIG. 18B

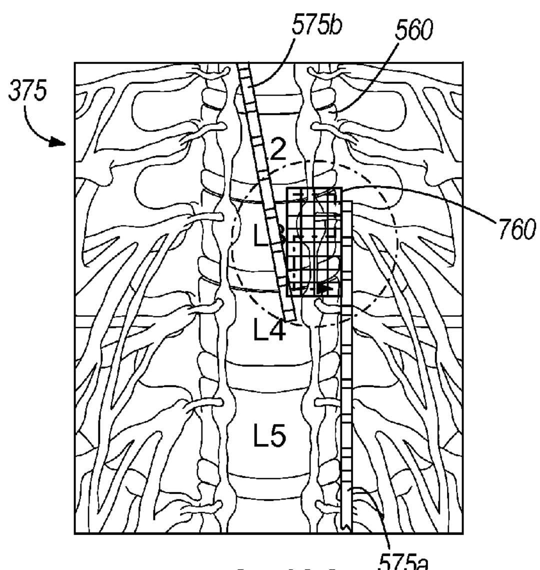


FIG. 18C

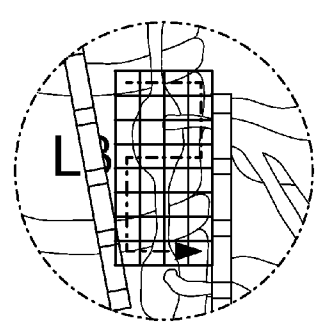


FIG. 18D

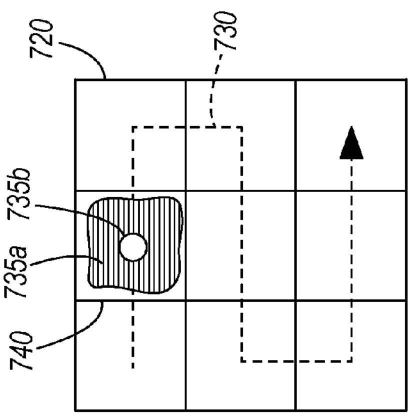


FIG. 19A

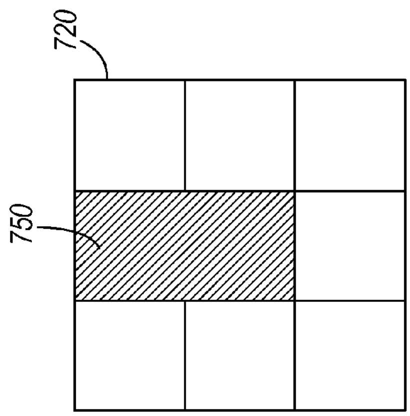


FIG. 19B

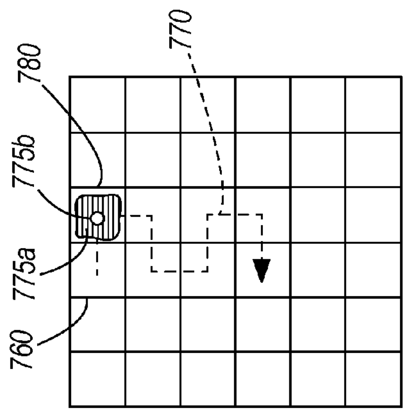


FIG. 19C

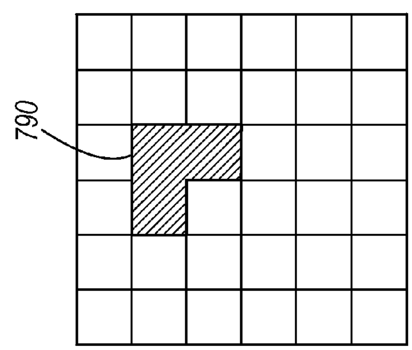


FIG. 19D

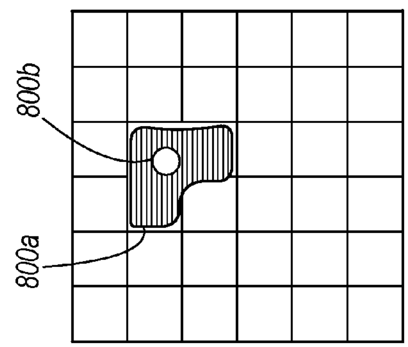


FIG. 19E

AUTOMATED SEARCH TO IDENTIFY A LOCATION FOR ELECTRICAL STIMULATION TO TREAT A PATIENT

RELATED APPLICATION

This application is a continuation of U.S. patent application Ser. No. 13/226989, filed Sep. 7, 2011, now U.S. Pat. No. 8,483,836, the content of which is incorporated herein by reference in its entirety.

BACKGROUND

The invention relates to a stimulation system, such as a spinal cord stimulation (SCS) system, having a tool for programming an electrical stimulation generator, such as an implantable pulse generator (IPG), of the system. The invention also relates to a method for developing a program for the stimulation system.

A spinal cord stimulator is a device used to provide electrical stimulation to the spinal cord or spinal nerve neurons for managing pain. The stimulator includes an implanted or external pulse generator and an implanted medical electrical lead having one or more electrodes at a distal location thereof. The pulse generator provides the stimulation through the electrodes via a body portion and connector of the lead. Spinal cord stimulation programming is defined as the discovery of the stimulation electrodes and parameters that provide the best possible pain relief (or paresthesia) for the patient using one or more implanted leads and its attached pulse generator. The programming is typically achieved by selecting individual electrodes and adjusting the stimulation parameters, such as the shape of the stimulation waveform, amplitude of current in mA (or amplitude of voltage in V), pulse width in microseconds, frequency in Hz, and anodic or cathodic stimulation.

With newer medical electrical leads having an increased number of electrodes, the electrode and parameter combination increases exponentially. This results in a healthcare professional, such as a clinician, requiring a substantial amount of time for establishing a manually created program for providing therapeutic spinal cord stimulation. Therefore, a manual approach for creating a program is not an optimal solution for the SCS system.

SUMMARY

Numerous embodiments of the invention provide a method and system for programming an SCS system with a substantially reduced time requirement, increased accuracy, and reduced power requirements.

In some embodiments, the invention provides an automated search method to identify a location for electrical stimulation to treat a patient with a stimulation system. The stimulation system includes an electrical stimulation generator, a first electrical contact and a second electrical contact implanted in the patient and coupled to the electrical stimulation generator, a programmer with a display screen, and a patient feedback device configured to communicate with the programmer.

The method includes displaying an image of a spinal column on the display screen of the programmer. The programmer determines a position of the first and second electrical contacts with respect to the spinal column and displays a set of regions on the image. The system provides electrical stimulation to each region of the set of regions using the first and second electrical contacts. The programmer then receives feedback from the patient indicating the effectiveness of the electrical stimulation to each region of the set of regions. The programmer further displays a set of subregions on the image within a subset of the set of regions, wherein the subset is chosen based on the feedback from the patient. The system provides electrical stimulation to each subregion of the set of subregions using the first and second electrical contacts. The programmer then receives additional feedback from the patient indicating the effectiveness of the electrical stimulation to each subregion of the set of subregions and identifies a subset of the set of subregions for targeted electrical stimulation based on the additional feedback from the patient.

In other embodiments, the invention provides a stimulation system for providing electrical stimulation to treat a patient. The stimulation system includes an electrical stimulation generator, a medical lead coupled to the electrical stimulation generator, and a programmer. The programmer includes a communication interface, a display screen, and a user interface. The communication interface communicates with the electrical stimulation generator to generate electrical stimulation. The display screen displays an image of a spinal column and a position of the medical lead relative to the spinal column. The user interface receives patient feedback. The programmer further displays a set of regions on the image and causes the electrical stimulation generator to provide electrical stimulation to each region of the set of regions using the medical lead. The programmer then receives patient feedback indicating the effectiveness of the electrical stimulation to each region of the set of regions. The programmer further displays a set of subregions on the image within a subset of the set of regions, wherein the subset is chosen based on the patient feedback and causes the electrical stimulation generator to provide electrical stimulation to each subregion of the set of subregions using the first and second electrical contacts. The programmer then receives additional patient feedback indicating the effectiveness of the electrical stimulation to each subregion of the set of subregions. The programmer then identifies a subset of the set of subregions for targeted electrical stimulation based on the additional patient feedback.

In other embodiments, the invention provides a programmer of a stimulation system for providing electrical stimulation to treat a patient. The stimulation system includes an electrical stimulation generator and a medical lead coupled to the electrical stimulation generator. The programmer includes a communication interface that communicates with the electrical stimulation generator to generate electrical stimulation, a display screen that displays an image of a tissue (such as a spinal column) and a position of the medical lead relative to the tissue, and a user interface that receives patient feedback. The programmer displays a set of regions on the image, causes the electrical stimulation generator to provide electrical stimulation to each region of the set of regions using the medical lead, and receives patient feedback indicating the effectiveness of the electrical stimulation to each region of the set of regions. Thereafter, the programmer displays a set of subregions on the image within a subset of the set of regions, wherein the subset is chosen based on the patient feedback, causes the electrical stimulation generator to provide electrical stimulation to each subregion of the set of subregions using the medical lead, and receives additional patient feedback indicating the effectiveness of the electrical stimulation to each subregion of the set of subregions. The programmer then identifies a subset of the set of subregions for targeted electrical stimulation based on the additional patient feedback.

Other aspects of the invention will become apparent by consideration of the detailed description and accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a partial perspective view of a patient using a spinal cord stimulation system.

FIG. **2** is a perspective view of an in-line lead for use in the spinal cord stimulation system of FIG. **1**.

FIG. **3** is a perspective view of a paddle lead for use in the spinal cord stimulation system of FIG. **1**.

FIG. **4** is a block diagram of a patient-feedback device for use in the spinal cord stimulation system of FIG. **1**.

FIG. **5** is a block diagram of an implantable pulse generator for use in the spinal cord stimulation system of FIG. **1**.

FIG. **6** is a block diagram of a clinician programmer for use in the spinal cord stimulation system of FIG. **1**.

FIG. **7** is a flow diagram for providing electrical stimulation to a patient.

FIG. **8** is a flow diagram for identifying a location for receiving electrical stimulation.

FIGS. **9**A-C illustrate a graphical user interface for identifying a location for receiving electrical stimulation.

FIG. **10** illustrates a graphical user interface that displays a location for receiving electrical stimulation.

FIG. **11** is a flow diagram for positioning medical leads on a patient and modeling a stimulation field.

FIGS. **12**A-I illustrate a graphical user interface for modeling the position of medical leads and electrical stimulation on a patient spinal column.

FIG. **13** illustrates an original image and a scaled image of a spinal column.

FIG. **14** illustrates the transmission of lead data and image data between a first programmer, an implanted pulse generator, and a second programmer.

FIG. **15** is a flow diagram for manual programming with a graphical user interface.

FIGS. **16**A-D illustrate a graphical user interface for programming electrical stimulation.

FIG. **17** is a flow diagram for automated programming with a graphical user interface.

FIGS. **18**A-C illustrate a graphical user interface for automated programming.

FIG. **18**D depicts a close-up view of a portion of the graphical user interface of FIG. **18**C.

FIGS. **19**A-E also illustrate a graphical user interface for automated programming.

DETAILED DESCRIPTION

Before any embodiments of the invention are explained in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of components set forth in the following description or illustrated in the following drawings. The invention is capable of other embodiments and of being practiced or of being carried out in various ways.

The invention herein relates to an electrical stimulation system for providing stimulation to target tissue of a patient. The system described in detail below is a spinal cord stimulation (SCS) system for providing electrical pulses to the neurons of the spinal cord of a patient. However, many aspects of the invention are not limited to spinal cord stimulation. The electrical stimulation system may provide stimulation to other body portions including a muscle or muscle group, nerves, the brain, etc.

FIG. **1** shows a spinal cord stimulation system **100** in use with a patient **105**. The system **100** includes one or more implanted medical electrical leads **110** connected to an implantable pulse generator (IPG) **115** or external pulse generator (EPG) **115**A. The leads **110** include an electrode array **120** at a distal end of the base lead cable. The electrode array **120** includes one or more electrical stimulation electrodes (may also be referred as electrode contacts or simply electrodes) and is placed adjacent to the dura of the spine **125** using an anchor. The spinal column includes the C1-C7 (cervical), T1-T12 (thoracic), L1-L5 (lumbar) and S1-S6 (sacral) vertebrae and the electrode array(s) **120** may be positioned anywhere along the spine **125** to deliver the intended therapeutic effects of spinal cord electrical stimulation in a desired region of the spine. The electrodes (discussed further in FIGS. **2** and **3**) of the electrode arrays **120** promote electrical stimulation to the neurons of the spine based on electrical signals generated by the IPG **115**. In one construction, the electrical signals are regulated current pulses that are rectangular in shape. However, the electrical signals can be other types of signals, including other types of pulses (e.g., regulated voltage pulses), and other shapes of pulses (e.g., trapezoidal, sinusoidal). The stimulation is provided from the IPG **115** to the electrodes via the base lead, which is connected to the IPG **115** with the proximal end of the base lead. The body of the lead can traverse through the body of the patient via the spinal column and from the spinal column through the body of the patient to the implant site of the IPG **115**.

The IPG **115** generates the electrical signals through a multiplicity of electrodes (e.g., four, eight, sixteen, twenty-four electrodes). The IPG **115** can control, for example, six aspects of electrical stimulation based on a program (may also be referred to as a protocol): on/off, amplitude (e.g., current or voltage), frequency, pulse width, pulse shape, and polarity (anodic or cathodic stimulation). The stimulation most discussed herein is a regulated (or constant) current that provides a square wave, cathodic stimulation with a variable amplitude, frequency, and/or pulse width. Typically, the IPG **115** is implanted in a surgically made pocket (e.g., in the abdomen) of the patient. However, the pulse generator can also be the EPG **115**A.

The IPG **115** communicates with any one of a clinician programmer (CP) **130**, a patient programmer and charger (PPC) **135**, and a pocket (or fob) programmer (PP) **140**. As discussed in further detail below, the CP **130** interacts with the IPG **115** to develop a program for stimulating the patient. The developing of the program is assisted with the use of a patient-feedback device (PFD) **145**. Once a program is developed, the program may be stored at the IPG **115**. The PPC **135** or the PP **140** can activate, deactivate, or perform limited changes to the programming parameters of the program. The PPC **135** is also used for charging the IPG **115**.

For the construction described herein, the IPG **115** includes a rechargeable, multichannel, radio-frequency (RF) programmable pulse generator housed in a metallic (e.g., titanium) case or housing. The metallic case is sometimes referred to as the "can" and may act either as a cathode or an anode or floating to the electrical contacts.

Referring now to FIGS. **2** and **3**, the figures show two exemplary leads **110**A and **110**B, respectively, that can be used in the SCS system. A first common type of lead **110** is the "in-line" lead shown in FIG. **2**. An in-line lead **110**A includes individual electrodes **150**A along the length of a flexible cable **155**A. A second common type of lead **110** is the "paddle" lead shown in FIG. **3**. In general, the paddle lead **110**B is shaped with a wide platform **160**B on which a variety of electrode **150**B configurations are situated. For example, the paddle lead **110**B shown in FIG. **3** has two columns of four rectangular shaped electrodes **150**B. A paddle lead typically contains contacts on one side only, but is not restricted to individual electrodes on either side, or electrodes perforating the carrier material.

For both leads shown in FIGS. **2** and **3**, a flexible cable **155**A or **155**B has respective small wires for the electrodes **150**A or **150**B. The wires are embedded within the cable **155**A or **155**B and carry the electrical stimulation from the IPG **115** to the electrodes **150**A or **150**B.

It is envisioned that other types of leads **110** and electrode arrays **120** can be used with the invention. Also, the number of electrodes **150** and how the electrodes **150** are arranged in the electrode array **120** can vary from the examples discussed herein.

The leads shown in FIGS. **2** and **3** are multiple channel leads. Here, a "channel" is defined as a specified electrode **150**, or group of electrodes **150**, that receives a specified pattern or sequence of electrical stimuli. For simplicity, this description will focus on each electrode **150** and the IPG's **115** metallic housing providing a respective channel. When more than one channel is available, each channel may be programmed to provide its own stimulus to its defined electrode.

There are many instances when it is advantageous to have multiple channels for stimulation. For example, different pain locations (e.g., upper extremities, lower extremities) of the patient may require different stimuli. Further, some patients may exhibit conditions better suited to "horizontal" stimulation paths, while other patients may exhibit conditions better suited to "vertical" stimulation paths. Therefore, multiple electrodes positioned to provide multiple channels can cover more tissue/neuron area, and thereby provide better stimulation program flexibility to treat the patient.

It is also envisioned that the number of leads **110** can vary. For example, one, two, or more leads **110** can be connected to the IPG **115**. The electrode arrays **120** of the leads **110**, respectively, can be disposed in different vertical locations on the spine **125** with respect to a vertical patient **105**, can be disposed horizontally (or "side-by-side") on the spine **125** with respect to a vertical patient **105**, or some combination thereof.

In alternative to the IPG **115**, the leads **110** can receive electrical stimuli from the EPG **115**A (also referred to a trial stimulator) through one or more percutaneous lead extensions. The EPG **115**A may be used during a trial period.

In one specific construction, a single lead **110**B having a two-by-four electrode paddle (as shown in FIG. **3**) is secured to the thoracic portion of the spine **125**. An IPG **115** having a metallic housing is disposed within the patient **105**. The housing acts as another electrode in this contemplated SCS system **100**. Thus, this arrangement results in nine electrodes total. Also, the specifically-discussed system includes nine channels formed by the eight electrodes of the electrode array **120**, respectively, and the metallic housing of the IPG **115**. However, it contemplated that a different number of leads, electrodes, and channels fall within the scope of the invention.

Referring back to FIG. **1**, a user provides feedback to the CP **130** with a PFD **145** while the CP **130** develops the program for the IPG **115**. In FIG. **1**, the PFD **145** is an ergonomic handheld device having a sensor (also referred to as input) **165**, a controller, and a communications output **175**. The sensor **165** can take the form of a discrete switch or can take the form of a continuously variable input, such as through the use of a strain gauge. It is envisioned that the use of a continuously variable input can provide magnitude information, thereby providing feedback information.

FIG. **4** provides a block diagram of an exemplary handheld PFD **145** used in the SCS system **100**. The PFD **145** includes two inputs **900** and **905** in communication with the housing of the device **145** and one input **910** internal to the housing. One of the external inputs **900** is a binary ON/OFF switch, preferably activated by the patient's thumb, to allow the patient **105** to immediately deactivate stimulation. The second input **905** includes a force or displacement sensor sensing the pressure or force exerted by the patient's hand. The sensed parameter can be either isotonic (constant force, measuring the distance traversed) or isometric (measuring the force, proportional to pressure applied by patient **105**). The resulting signal from the sensor **905** is analog and, therefore, the signal is conditioned, amplified, and passed to a microcontroller via an analog-to-digital converter.

The internal input **910** for the PFD **145** of FIG. **4** is a motion sensor. The sensor **910**, upon detecting motion, initiates activation of the PFD **145**. The device **145** stays active until movement is not detected by the sensor **910** for a time period. Alternatively, the PFD can be activated/deactivate by an on-off button. Power is provided by an internal battery **920** that can be replaceable and/or rechargeable.

The processing of the inputs from the sensors **900** and **905** take place in a controller, such as a microcontroller **925**. The microcontroller **925** includes a suitable programmable portion **930** (e.g., a microprocessor or a digital signal processor), a memory **935**, and a bus **940** or other communication lines. Output data of the microcontroller **925** is sent via a Bluetooth bi-direction radio communication portion **945** to the CP **130**. The Bluetooth portion **945** includes a Bluetooth communication interface, an antenna switch, and a related antenna, all of which allows wireless communication following the Bluetooth Special Interest Group standard. Other outputs may include indicators (such as light-emitting diodes) for communicating stimulation activity **950**, sensor activation **955**, and device power **960**, and a speaker and related circuitry **965** for audible feedback.

As discussed further below, the patient **105** provides feedback to the SCS system **100**, and specifically the CP **130**, while the CP **130** establishes the program for the IPG **115**. The patient **105** can activate the PFD **145** when the patient **105** feels various stimuli, such as paresthesia or pain.

Other means can be used for receiving patient feedback. For example, a patient can provide feedback using a mouth-piece that is inserted into the mouth of the patient, where the mouth-piece enables the user to provide feedback by biting the mouthpiece. Additionally, a patient can use an optical sensor (such as a camera and related image processing software) that detects visual cues from a patient, such as blinking of the patient's eyes, and/or a foot pedal that receives input by the patient manipulating a switch with his foot. It is also envisioned that the patient may provide feedback directly through the touch screen or hard buttons on the CP **130**.

As discussed earlier, it should be understood that aspects of the SCS system **100** can be applied to other types of electrical stimulation systems. That is, other electrical stimulation systems provide electrical stimuli to other types of target tissues. Similar to the SCS system **100**, these other electrical stimulation systems include one or more medical electrical leads having electrodes, a stimulation generator coupled to the one or more medical electrical leads, and a clinician programmer for establishing a program with the stimulation generator.

FIG. **5** shows a block diagram of one construction of the IPG **115**. The IPG **115** includes a printed circuit board ("PCB") that is populated with a plurality of electrical and electronic components that provide power, operational control, and protection to the IPG **115**. With reference to FIG. **5**, the IPG **115** includes a communication portion **200** (also referred to as a communication unit) having a transceiver **205**, a matching network **210**, and antenna **212**. The communication portion **200** receives power from a power ASIC (discussed below), and communicates information to/from the microcontroller **215** and a device (e.g., the CP **130**) external to the IPG **115**. For example, the IPG **115** can provide bi-direction radio communication capabilities, including Medical Implant Communication Service (MICS) bi-direction radio communication following the MICS specification.

The IPG **115**, as previously discussed, provides stimuli to electrodes **150** of an implanted medical electrical lead **110**. As shown in FIG. **5**, N electrodes are connected to the IPG **115**. In addition, the enclosure or housing **220** of the IPG **115** can act as an electrode. The stimuli are provided by a stimulation portion **225** in response to commands from the microcontroller **215**. The stimulation portion **225** includes a stimulation application specific integrated circuit (ASIC) **230** and circuitry including blocking capacitors and an over-voltage protection circuit. As is well known, an ASIC is an integrated circuit customized for a particular use, rather than for general purpose use. ASICs often include processors, memory blocks including ROM, RAM, EEPROM, Flash, etc. The stimulation ASIC **230** can include a processor, memory, and firmware for storing preset pulses and programs that can be selected via the microcontroller **215**. The providing of the pulses to the electrodes **150** is controlled through the use of a waveform generator and amplitude multiplier of the stimulation ASIC **230**, and the blocking capacitors and overvoltage protection circuitry of the stimulation portion **225**, as is known in the art. The stimulation portion **225** of the IPG **115** receives power from the power ASIC (discussed below). The stimulation ASIC **230** also provides signals to the microcontroller **215**. More specifically, the stimulation ASIC **230** can provide impedance values for the channels associated with the electrodes **150**, and also communicate calibration information with the microcontroller **215** during calibration of the IPG **115**.

The IPG **115** also includes a power supply portion **240**. The power supply portion includes a rechargeable battery **245**, fuse **250**, power ASIC **255**, recharge coil **260**, rectifier **263** and data modulation circuit **265**. The rechargeable battery **245** provides a power source for the power supply portion **240**. The recharge coil **260** receives a wireless signal from the PPC **135**. The wireless signal includes an energy that is converted and conditioned to a power signal by the rectifier **263**. The power signal is provided to the rechargeable battery **245** via the power ASIC **255**. The power ASIC **255** manages the power for the IPG **115**. The power ASIC **255** provides one or more voltages to the other electrical and electronic circuits of the IPG **155**. The data modulation circuit **265** controls the charging process.

The IPG also includes a magnetic sensor **280**. The magnetic sensor **280** provides a "hard" switch upon sensing a magnet for a defined period. The signal from the magnetic sensor **280** can provide an override for the IPG **115** if a fault is occurring with the IPG **115** and is not responding to other controllers.

The IPG **115** is shown in FIG. **5** as having a microcontroller **215**. Generally speaking, the microcontroller **215** is a controller for controlling the IPG **115**. The microcontroller **215** includes a suitable programmable portion **285** (e.g., a microprocessor or a digital signal processor), a memory **290**, and a bus or other communication lines. An exemplary microcontroller capable of being used with the IPG is a model MSP430 ultra-low power, mixed signal processor by Texas Instruments. More specifically, the MSP430 mixed signal processor has internal RAM and flash memories, an internal clock, and peripheral interface capabilities. Further information regarding the MSP 430 mixed signal processor can be found in, for example, the "MSP430G2x32, MSP430G2x02 MIXED SIGNAL MICROCONTROLLER" data sheet; dated December 2010, published by Texas Instruments at www.ti.com; the content of the data sheet being incorporated herein by reference.

The IPG **115** includes memory, which can be internal to the control device (such as memory **290**), external to the control device (such as serial memory **295**), or a combination of both. Exemplary memory include a read-only memory ("ROM"), a random access memory ("RAM"), an electrically erasable programmable read-only memory ("EEPROM"), a flash memory, a hard disk, or another suitable magnetic, optical, physical, or electronic memory device. The programmable portion **285** executes software that is capable of being stored in the RAM (e.g., during execution), the ROM (e.g., on a generally permanent basis), or another non-transitory computer readable medium such as another memory or a disc.

Software included in the implementation of the IPG **115** is stored in the memory **290**. The software includes, for example, firmware, one or more applications, program data, one or more program modules, and other executable instructions. The programmable portion **285** is configured to retrieve from memory and execute, among other things, instructions related to the control processes and methods described below for the IPG **115**. For example, the programmable portion **285** is configured to execute instructions retrieved from the memory **290** for sweeping the electrodes **150** in response to a signal from the CP **130**.

The PCB also includes a plurality of additional passive and active components such as resistors, capacitors, inductors, integrated circuits, and amplifiers. These components are arranged and connected to provide a plurality of electrical functions to the PCB including, among other things, filtering, signal conditioning, or voltage regulation, as is commonly known.

FIG. **6** shows a block diagram of one construction of the CP **130**. The CP **130** includes a printed circuit board ("PCB") that is populated with a plurality of electrical and electronic components that provide power, operational control, and protection to the CP **130**. With reference to FIG. **6**, the CP includes a processor **300**. The processor **300** is a controller for controlling the CP **130** and, indirectly, the IPG **115** as discussed further below. In one construction, the processor **300** is an applications processor model i.MX515 available from Freescale Semiconductor. More specifically, the i.MX515 applications processor has internal instruction and data caches, multimedia capabilities, external memory interfacing, and interfacing flexibility. Further information regarding the i.MX515 applications processor can be found in, for example, the "IMX51CEC, Rev. 4" data sheet; dated August 2010; published by Freescale Semiconductor at www.freescale.com, the content of the data sheet being incorporated herein by reference. Of course, other processing units, such as other microprocessors, microcontrollers, digital signal processors, etc., can be used in place of the processor **300**.

The CP **130** includes memory, which can be internal to the processor **300** (e.g., memory **305**), external to the processor **300** (e.g., RAM **310**), or a combination of both. Exemplary memory include a read-only memory ("ROM"), a random access memory ("RAM"), an electrically erasable programmable read-only memory ("EEPROM"), a flash memory, a hard disk, or another suitable magnetic, optical, physical, or electronic memory device. The processor **300** executes software that is capable of being stored in the RAM (e.g., during execution), the ROM (e.g., on a generally permanent basis), or another non-transitory computer readable medium such as another memory or a disc. The CP **130** also includes input/output ("I/O") systems that include routines for transferring information between components within the processor **300** and other components of the CP **130** or external to the CP **130**.

Software included in the implementation of the CP **130** is stored in the memory **305** of the processor **300**, RAM **310**, ROM **315**, or external to the CP **130**. The software includes, for example, firmware, one or more applications, program data, one or more program modules, and other executable instructions. The processor **300** is configured to retrieve from memory and execute, among other things, instructions related to the control processes and methods described below for the CP **130**. For example, the processor **300** is configured to execute instructions retrieved from the memory **305**, RAM **310**, and/or ROM **315** for establishing a program to control the IPG **115**.

One memory shown in FIG. **6** is RAM **310**, which can be a double data rate (DDR2) synchronous dynamic random access memory (SDRAM) for storing data relating to and captured during the operation of the CP **130**. In addition, a secure digital (SD) or multimedia card (MMC) can be coupled to the CP for transferring data from the CP to the memory card via slot **315**. Of course, other types of data storage devices can be used in place of the data storage devices shown in FIG. **6**.

The CP **130** includes multiple bi-directional radio communication capabilities. Specific wireless portions included with the CP **130** are a Medical Implant Communication Service (MICS) bi-direction radio communication portion **320**, a WiFi bi-direction radio communication portion **325**, and a Bluetooth bi-direction radio communication portion **330**. The MICS portion **320** includes a MICS communication interface, an antenna switch, and a related antenna, all of which allows wireless communication using the MICS specification. The WiFi portion **325** and Bluetooth portion **330** include a WiFi communication interface, a Bluetooth communication interface, an antenna switch, and a related antenna all of which allows wireless communication following the WiFi Alliance standard and Bluetooth Special Interest Group standard. Of course, other wired, wireless local area network (WLAN) standards, and wireless personal area networks (WPAN) standards can be used with the CP **130**.

The CP **130** includes three hard buttons: a "home" button **335** for returning the CP to a home screen for the device, a "quick off" button **340** for quickly deactivating stimulation IPG, and a "reset" button **345** for rebooting the CP **130**. The CP **130** also includes an "ON/OFF" switch **350**, which is part of the power generation and management block (discussed below).

The CP **130** includes multiple communication portions for wired communication. Exemplary circuitry and ports for receiving a wired connector include a portion and related port for supporting universal serial bus (USB) connectivity **355**, including a Type-A port and a Micro-B port; a portion and related port for supporting Joint Test Action Group (JTAG) connectivity **360**, and a portion and related port for supporting universal asynchronous receiver/transmitter (UART) connectivity **365**. Of course, other wired communication standards and connectivity can be used with or in place of the types shown in FIG. **6**.

Another device connectable to the CP **130**, and therefore supported by the CP **130**, is an external display. The connection to the external display can be made via a micro High-Definition Multimedia Interface (HDMI) **370**, which provides a compact audio/video interface for transmitting uncompressed digital data to the external display. The use of the HDMI connection **370** allows the CP **130** to transmit video (and audio) communication to an external display. Of course other connection schemes, such as DVI, can be used with the CP **130**.

The CP **130** includes a touch screen I/O device **375** for providing a user interface with the clinician. The touch screen display **375** can be a liquid crystal display (LCD) having a resistive, capacitive, or similar touch-screen technology. It is envisioned that multitouch capabilities can be used with the touch screen display **375** depending on the type of technology used.

The CP **130** includes a camera **380** allowing the device to take pictures or video. The resulting image files can be used to document a procedure or an aspect of the procedure. For example, the camera **380** can be used to take pictures of barcodes associated with the IPG **115** or the leads **110**, or documenting an aspect of the procedure, such as the positioning of the leads. Similarly, it is envisioned that the CP **130** can communicate with a fluoroscope or similar device to provide further documentation of the procedure. Other devices can be coupled to the CP **130** to provide further information, such as scanners or RFID detection. Similarly, the CP **130** includes an audio portion **385** having an audio codec circuit, audio power amplifier, and related speaker for providing audio communication to the user, such as the clinician or the surgeon.

The CP **130** further includes a power generation and management block **390**. The power block **390** has a power source (e.g., a lithium-ion battery) and a power supply for providing multiple power voltages to the processor, LCD touch screen, and peripherals.

As best shown in FIG. **1**, the CP **130** is a handheld computing tablet with touch screen capabilities. The tablet is a portable personal computer with a touch screen, which is typically the primary input device. However, an external keyboard or mouse can be attached to the CP **130**. The tablet allows for mobile functionality not associated with even typical laptop personal computers, which can be used in some embodiments of the invention.

In operation, the IPG **115** (or the EPG **115**A) through the use of the implanted medical electrical leads **110**, and specifically the electrodes **150**, stimulates neurons of the spinal cord **125**. The IPG **115** selects an electrode stimulating configuration, selects a stimulation waveform, regulates the amplitude of the electrical stimulation, controls the width and frequency of electrical pulses, and selects cathodic or anodic stimulation. This is accomplished by a healthcare professional (e.g., a clinician), using the CP **130**, setting the parameters of the IPG **115**. The setting of parameters of the IPG results in a "program" for the electrode stimulation. Programming may result in multiple programs that the patient can choose from. Having multiple programs allows, for example, the patient to find a best setting for paresthesia at a particular time of treatment.

With reference to FIG. **3**, an electrode array **120** includes eight electrodes **150**B. The shown electrode array **120** has two columns and four rows as viewed along a longitude length of the lead **110**. More generically, the lead includes cl columns and r rows, where cl is two and r is four. When referring to a particular column, the column is referred to herein as the j-th column, and when referring to a particular row, the row is referred to as the i-th row.

Before proceeding further, it should be understood that not all electrode arrays **120** are conveniently shaped as a simple matrix having definite columns and definite rows. More complex configurations are possible, which are referred to herein as complex electrode array configurations. The processes discussed herein can account for complex electrode array configurations. For example, a representative array having cl columns and r rows for a complex electrode array configuration may include "dummy" addresses having "null" values in the array. For a specific example, an electrode contact may span multiple columns. The resulting array may have a first address i, j representing the multiple column electrode and a second address i, j+1 having a "null" value to account for the multiple columns of the multiple column electrode. This concept can be expanded to even more complex arrangements. Accordingly, all electrode arrays **120** can be addressed as a matrix and it will be assumed in the discussion below that the electrode array **120** has been addressed as a matrix.

FIG. **7** illustrates a method **500** of providing electrical stimulation to a patient using, for example, the spinal cord stimulation system **100** described above. The method **500** begins with identifying a location on the spinal cord of the patient **105** to receive stimulation (step **505**). In step **510**, the location of medical leads **110** implanted in the patient **105** is determined and positioned on a patient model displayed on a graphical user interface (GUI) (e.g., on display **375** of CP **130**). In step **515**, a user selects whether to proceed with manual configuration of the stimulation (step **520**) or with an automated search for identify preferred stimulation programming (step **525**). After proceeding with steps **520** and **525**, the user may return to step **515**.

Before proceeding further, it should be understood that the steps discussed in connection with FIG. **7** above and with FIGS. **8**, **11**, **15**, and **17** below will be discussed in a generally iterative manner for descriptive purposes. However, various steps described herein with respect to the process of FIGS. **8**, **11**, **15**, and **17** are capable of being executed simultaneously or in an order that differs from the illustrated serial and iterative manner of discussion. It is also envisioned that not all steps are required as described below. For instance, each of the steps of method **500** may be implemented alone, in combination with other steps, or in a different order than set forth in FIG. **7**. As shown in FIG. **7**, methods **510**, **520**, and method **525** may be carried out in series. However, the methods **510**, **520**, and **525** are shown in FIGS. **11**, **15**, and **17**, respectively, to include steps that are nearly duplicative to one another. For example, steps **510***a* to **510***f* are similar to steps **520***a* to **520***f*. Thus, if method **510** as shown in FIG. **11** were executed first, then method **520** as shown in FIG. **15**, steps **510***a* to **510***f* would, in essence, be executed a second time when steps **520***a* and **520***f* are performed. The methods are illustrated in this manner to highlight the independence of methods **510**, **520**, and **525**. However, when carrying out methods **510**, **520**, and **525** in series as shown in FIG. **7**, at least in some instances, such repetitive steps are not re-executed. For example, in executing the methods **510** and **520** in series, as shown in FIG. **7**, at least in some instances, either steps **510***a* to **510***f* or steps **520***a* to **520***f*, but not both, are executed.

FIG. **8** illustrates step **505** (also referred to as method **505**) in greater detail. In step **505***a*, a patient model is displayed on a display device. For instance, an image of a human may be shown on the touch screen display **375** of the CP **130**. The user (e.g., the patient **105** or another on behalf of the patient) may request alternate views of the patient model **530**, such as a front or back view as illustrated in FIGS. **9**A and **9**B, respectively. Additionally, the patient may magnify various portions of the patient model **530** to view the portion in more detail. FIGS. **9**A-C depict various views of a patient model **530** as displayed on touch screen display **375** including a front, back, and magnified view.

In step **505***b*, the user selects an area on the patient model **530** that corresponds to an area of pain on the patient **105**. The user may make the selection via the touch screen capabilities of the touch screen display **375**, or another user input of the CP **130** (e.g., mouse, keyboard, etc.). The user may more generally select an area on the patient model **530** to request a magnified view (e.g., FIG. **9**C) and, thereafter, indicate the location of pain on the patient model **530** more particularly.

Upon receiving the user indication of the area of pain on the patient model **530**, the CP **130** associates the area of pain with a spinal cord location in step **505***c*. For instance, the CP **130** accesses a database that receives as input a body part location and returns as output an associated spinal cord location. The database may be stored locally (e.g., in memory **305**) or remotely (e.g., accessible via an Internet or local network connection). For instance, in FIGS. **9**A and **9**B, in response to user input selecting the mid-thigh of the right leg of the patient model **530**, the CP **130** associates the selection with the L3 vertebrae and the lumbar plexus. The CP **130** may also indicate the association in step **505***c* by, e.g., a textual or image output. Additionally, the user may specify the type of nerves being listed or highlighted. For instance, in response to the user selecting one of a sensory, motor, and root graphical buttons **534**, the CP **130** lists and/or highlights on the patient model **530** the sensory, motor, and root nerves, respectively, associated with the area of pain indicated by the user input. In some instances, the CP **130** includes a representation of the spinal column **533** that can be used to highlight the associated location on the spinal column determined in step **505***c*.

In step **505***d*, the CP **130** determines a suggested stimulation area to stimulate the associated spinal cord location. A database may store suggested stimulation areas such that the database receives as input a spinal cord location and provides as output the suggested stimulation area. The database may be the same database referred to with respect to step **505***c*. In some embodiments, steps **505***c* and **505***d* are combined into a single step. In other words, an identified pain location is input to the CP **130** and the CP **130** determines a suggested stimulation area without first associating the pain area with a spinal cord location. The steps of associating may be performed by an association module (not shown) of the CP **130**.

In step **505***e*, the determined stimulation area is displayed to the user and/or patient. For instance, FIG. **10** depicts an anatomically correct spinal column **535** representation of the patient and a suggested stimulation field **540** including a target area **545** near the L3 vertebrae. The term "anatomically correct" means a generally realistic representation of the particular patient's anatomy or an actual image (e.g., x-ray image) of the patient, rather than a generic image applicable to patients with significantly different anatomies. Thus, an anatomically correct image is scaled to a patient to accommodate differently sized patients or is otherwise customized to a particular patient or to particular characteristics associated with the patient.

Although method **505** is discussed as being implemented using the CP **130**, another computer device, such as a personal computer, laptop, tablet, smart phone, etc., may be used in method **505** either in place of or in combination with the CP **130**. For instance, the CP **130** may transmit user input to another computer device for remote computing or the CP **130** may access information remotely stored on another computer device to execute method **505**.

FIG. **11** illustrates step **510** (also referred to as method **510**) for modeling the position of one or more medical leads **110** (e.g., graphical leads **575***a* and **575***b*) on a patient model in greater detail. The position of one or more medical leads **110** are modeled based on actual medical leads **110** implanted within the patient **105**. Accurately modeling the actual placement of the medical leads **110** within the patient **105** assists a user in stimulation programming. With the input of stimulation parameters, the method **510** also enables modeling of stimulation generated by the medical leads **110**. This modeling further assists a user in stimulation programming. Additionally, the method **510** allows a user to model medical leads **110** and stimulation before actually implanting the medical leads **110** within the patient **105**. In turn, the method **510** assists a clinician in determining where to position leads **110** within the patient **105** to obtain desired stimulation. It is also envisioned that position modeling can be extended to other portions of the stimulation system, such as the IPG **115** for example.

The method **510** begins in step **510***a* with displaying an image of a spinal column **560** as shown in FIG. **12**A. For instance, the spinal column **560** may be displayed on the display **375** of the CP **130**. The user may specify patient information, such as height, weight, etc., such that the image of the spinal column **560** is scaled to be anatomically correct. Alternatively, the image of the spinal column **560** may be an actual fluoroscope or x-ray image received by the CP **130**. For instance, the user may take a picture of an x-ray with the camera **380** of the CP **130**, or the CP **130** may communicate with a fluoroscope or similar device to receive the image of the spinal column **560**. The CP **130** may further include image processing to convert the image into an appropriate format, to suppress unwanted details, to highlight desired aspects, or otherwise ready the image for display on the CP **130**.

In step **510***b*, the user inputs lead positioning input. The user first selects one or more lead types to be positioned on the patient model. The selected leads should generally represent the leads **110** already implanted in the patient **105** or leads that may potentially be implanted within the patient **105**. For example, the user may select one or more leads representing the in-line lead **110**A (FIG. **2**), the paddle lead **110**B (FIG. **3**), or another medical lead type.

Once the one or more leads are selected, in step **510***c*, they are overlaid on the image of the spinal column **560**, as shown in FIG. **12**B. In the FIG. **12**B example, the user has selected two in-line type leads (representing in-line leads **110**A), which are shown as leads **575***a* and **575***b*. In step **510***d*, the user indicates whether he or she has completed positioning the selected medical leads. If not, the method returns to step **510***b* to receive additional user input. In FIGS. **12**A-E, the user is able to "move" or "rotate" the leads **575***a* and **575***b* to position the lead on the spinal column **560**. For instance, using the touch screen display **375** or other input devices, the user is able to select a graphical lead and to cause its movement or rotation on the display **375**. The move button **585** and rotate button **590** alter the positioning action that the user may cause with respect to the graphical lead. As shown in FIG. **12**B and FIG. **12**C, with the move button **585** selected, the user moves the selected lead **575***b* upwards. In FIGS. **12**D and **12**E, with the rotate button **590** selected, the user rotates the selected lead **575***b* counter-clockwise. Additionally, the user may alter the size of the leads **575***a* and **575***b* by dragging the boundaries of the lead via the touch screen display **375** or other input device. In some instances, an additional "resize" graphic button, similar to the move button **585** and rotate button **590**, is shown on the display **375** such that the user can selectively enable/disable the ability to resize the leads **575***a* and **575***b*. Thus, the user is able to provide the CP **130** with positioning input to position the leads **575***a* and **575***b* in the anatomically correct position (e.g., the lead **575***b* is generally in the middle of the spinal column **560** along the L2, L3, and L4 vertebrae), in the anatomically correct orientation (e.g., the lead **575***b* is rotated slightly counterclockwise), and with the anatomically correct size (e.g., the lead **575***a* and **575***b* are the appropriate scale/size relative to the spinal column **560**).

In some instances, when an actual image of the patient, such as an x-ray or fluoroscope image, is received by the CP **130** in step **510***a*, the CP **130** may use image processing in step **510***b* to analyze the received image to identify the actual lead position, orientation, and size. The positioning input of the leads is received from an image processing module (not shown) of the CP **130**. Thereafter, in step **510***c*, the spinal column **560** and leads **575***a* and **575***b*, as identified, are displayed on the screen **375**. The user may still adjust the position of the leads **575***a* and **575***b* by cycling through steps **510***d*, **510***b*, and **510***c* as necessary. Additionally, the user may specify to the CP **130** the lead type(s) in step **510***b*, particularly if the CP **130** is not able to deduce the type based on the positioning input.

To indicate that the user has completed positioning the leads **575***a* and **575***b*, the user may select the show button **595**. The user may return to further modify the lead positions by again de-selecting the show button **595**. Other user actions may be used to indicate completion of lead positioning as well. The positions of the leads **575***a* and **575***b* may be transmitted and stored within the IPG **115** for later retrieval. The positions of the leads **575***a* and **575***b* may be represented using coordinates in an x-y coordinate system overlaid on the screen **375**. For instance, FIG. **12**I depicts x-y coordinates and an angle (A_X, A_Y, A_θ) for lead **575***a* and (B_X, B_Y, B_θ) for lead **575***b*, with the origin (0,0) positioned in the upper left portion of the screen **375**. The x-y-angle coordinates (A_X, A_Y, A_θ) and (B_X, B_Y, B_θ) indicate, respectively, the location of a reference point on the leads **575***a* and **575***b*, and an angle of an axis of the leads with respect to a vertical line (parallel with the y-axis) passing through the x-position of the reference point. The reference point may be, for instance, an electrode, a mid-point, an end-point, or another portion of the lead. Additionally, in some instances, multiple coordinates for each lead **575***a* and **575***b* are provided to indicate multiple reference points (e.g., electrodes) of the leads **575***a* and **575***b*. The locations of electrodes that were not specified by the coordinates can be deduced based on the position data (x-y-angle coordinates) received and based on knowledge of the particular lead type. Having the particular electrode locations allows the CP **130** to be aware of relative positions of the electrodes, which assists in modeling stimulation and determining desired stimulation parameters. Additional or alternative positioning information of the leads **575***a* and **575***b* may include the size of the leads (length, wide, height), number of electrodes, electrode positions along the leads, among other information.

Also transmitted to the IPG **115** can be an identifier for the spinal column representation used in the original positioning process or the image actually used in the positioning process. For example, the identifier can identify which representation, image, model, or map originally used to generate the position data, thereby allowing better rendering upon later retrieval. If the patient **105** later returns to a clinician for additional programming, the IPG **115** implanted in the patient **105** may communicate the position data (including the image or identifier) to the second (or subsequent) CP **130** of the clinician for rendering. If an identifier is used, the second CP **130** can use the identifier to select the same image used in the original positioning process for the subsequent positioning process. Thus, the communication of position data can replace step **510***b* of method **510** and eliminate the need to cycle through steps **502***b*-**520***d*, reducing the time needed for programming. The position data transferred to the second CP **130** can also assist in evaluating or performing a procedure on the patient

105. Moreover, the position data, even if just relational data, can be particularly useful when multiple leads are connected to the IPG **115**. The position data allows for a better representation of the interacting stimulation fields when stimulating the electrodes of each lead.

In some instances, a scaling parameter is sent along with the identifier of the spinal column representation or actual image used in the positioning process. Scaling an image enables a particular image to be used to represent patients of various sizes. For instance, FIG. **13** illustrates an original image **646** at 100% and a scaled image **647** at 125%. While the scaled image **647** is larger, a corresponding smaller area of the image is presented in the display **375** shown in the dashed rectangle) and the leads are not scaled. Alternatively, the scaling may be applied to the leads **575***a* and **575***b* instead of or in addition to the image to ensure proper proportional representation.

FIG. **14** illustrates a first CP **130***a* storing lead position data and image data on the IPG **115**, and a second CP **130***b* later retrieving the lead data and image data from the IPG **115**. As described above, a first CP **130***a* is used for initial programming of the IPG **115**. The initial programming includes storing lead data and image data on the IPG **115**. The lead data includes a lead identifier and position information for each lead. The image data includes an image identifier and a scaling parameter. Subsequently, a second CP **130***b* may receive from the IPG **115** the stored lead data and image data. The second CP **130***b* may then select and retrieve a copy of the image from an accessible image database (whether local or remote) using the image identifier. The second CP **130***b* then scales and displays the image according to the scaling parameter. The second CP **130***b* then selects and retrieves graphics of the leads from an accessible lead database (whether local or remote) based on the lead identifiers, and overlays the graphics according to their respective lead position data. In some instances, the graphics of the leads may be scaled according to a lead scaling parameter provided in addition to or in place of the image scaling parameter. Thus, the second CP **130***b* has recreates the image and leads as they were displayed on the first CP **130***a*. Thereafter, the second CP **130***b* can perform additional programming of the leads.

Once the user has completed positioning the leads **575***a* and **575***b* as determined in step **510***d*, the user enters stimulation parameters for the leads **575***a* and **575***b* in step **510***e*. In step **510***e*, the user indicates which electrodes on the medical leads are to be activated and whether each is an anode or cathode. The user may make these indications via the touch screen display **375** or other input devices of the CP **130**. For instance, the user may point to and select one or more electrodes to mark them for activation, and also indicate whether the electrode is an anode or cathode via other buttons of the user interface. Additionally, the user indicates the amplitude and pulse width for the electrical driving signals sent to the activated electrodes. FIG. **12**F depicts an amplitude control **600** and a pulse width control **605**, which each have a sliding tab **610** for the user to manipulate to indicate the desired amplitude and pulse width, respectively, for the selected lead. The control bars also have shutters **615** (left shutter **615***a* and right shutter **615***b*) that limit the minimum and maximum selectable amplitude and pulse width. The shutters **615** may be customized by the user or preprogrammed for a particular use, medical lead type, etc. In some instances, the amplitude and pulse width have default settings, such as the minimum potential amplitude and pulse width. The user may also program other stimulation parameters of leads **575***a* and **575***b*, such as frequency and pulse shape.

After the stimulation parameters are entered, in step **510***f*, an expected stimulation field **625**, based on the entered parameters, is determined and displayed on the display **375**. FIG. **12**F depicts the expected stimulation field **625** as described in relation to step **510***f*. As the intensity of the expected stimulation field **625** is increased (e.g., the amplitude increased and the "on" duty cycle of the pulse width increased), the more opaque the expected stimulation field **625** appears. Other colors or graphic alterations to the expected stimulation field **625** may be used in some implementations. Additionally, the user may further adjust the stimulation parameters and view the changes to the expected stimulation field in real-time. In other words, steps **510***e* and **510***f* may be repeated as desired by the user.

In step **510***g*, the user causes generation of a stimulation field via the user interface of the CP **130**. First, the user disables the stimulation lock button **635**. Once the stimulation lock button **635** is disabled (see FIG. **12**G), the user may enable the stimulate button **640**. When the stimulate button **640** is enabled, a stop button **645** replaces both the stimulation lock button **635** and the stimulate button **640** on the display **375**, and the expected stimulation field **625** (now representing actual stimulation) changes in appearance (e.g., it becomes more opaque), as shown in FIG. **12**H. Additionally, when the stimulate button **640** is enabled, the IPG **115** generates stimulation of the spinal cord according to the input stimulation parameters. For instance, the CP **130** transfers the stimulation parameters and instructions to the IPG **115** via one of the various communications interfaces described above. Selecting the stop button **645** on the display **375** ceases the stimulation and re-enable the stimulation lock button **635** as shown in FIG. **12**F.

FIG. **15** depicts a step **520** (also referred to as method **520**) for receiving user input to modify a graphical depiction of a stimulation field via a graphical user interface to generate and manipulate an actual stimulation field. The method **520** begins with steps **520***a*, **520***b*, **520***c*, **520***d*, **520***e*, and **520***f*, which are similar to steps **510***a*, **510***b*, **510***c*, **510***d*, **510***e*, and **510***f* of method **510**. Although the user inputs stimulation parameters in step **510***e*, default parameters may be used in place of or in combination with user input stimulation parameters in step **520***e*. Regardless, in step **520***f*, like **510***f*, a stimulation field **655** with target **660** resulting from the chosen or default stimulation parameters is displayed on the CP **130**, along with a spinal column **560**, as shown in FIG. **16**A.

In step **520***g*, the user manipulates the stimulation field **655** and/or target **660**. The user interface includes a shape button **670** and move button **675** to enable the user to specify the type of modification to the stimulation field **655** and/or target **660** that the user is able to perform. When the move button **675** is enabled, the user can move (pan) the entire stimulation field **655** and target **660** up, down, left, or right, either together or independently. For example, the user may drag the stimulation field **655** or target **660** (e.g., via a mouse or touch screen display **375** input) to move of the stimulation field **655** or target **660**. When the shape button **670** is enabled, the user can modify the shape of the stimulation field **655** and target **660**, together or independently. For example, the user may drag the boundaries of the stimulation field **655** or target **660** (e.g., via a mouse or touch screen display **375** input) to alter the shape of the stimulation field **655** or target **660**. These shape and position modifications are graphical manipulations, in that they include a user inputting commands into a graphical user interface to adjust a graphic depiction of stimulation. The graphical manipulations are then translated by the programmer **130** into changes for the stimulation parameters of the electrode array **120** to generate the stimulation field **655** and target **660** as graphically depicted. Graphical manipulations contrast with, for instance, a user manually adjusting stimulation parameters, such as amplitude and pulse width, by entering or adjusting numeric values (e.g., using the amplitude control **600** or pulse width control **605**).

FIGS. **16**A and **16**B, respectively, show the stimulation field **655** before and after the user modified the shape of the stimulation field **655** to decrease in size. FIGS. **16**B and **16**C, respectively, show the target **660** before and after the user modified the shape of the target to increase in size. Additionally, FIGS. **16**A and **16**B, respectively, show the target **660** before and after the user moved the target up and to the right.

In step **520***g*, the user is also able to modify the amplitude and pulse width of the stimulation field **655** using the amplitude control **600** and pulse width control **605**, as described above with respect to method **510**. FIG. **16**D depicts an increase in amplitude of the stimulation field **655** and target **660** relative to FIG. **16**C caused by a combination of (1) user manipulation of the amplitude control **600** and (2) moving the stimulation field **655** and target **660** downward to an area where the leads **575***a* and **575***b* are closer together. In general, the changes in the intensity of the stimulation field **655** and target **660** are illustrated by changing the appearances of each (e.g., by making each more opaque as intensity increases).

Once the user has completed the initial manipulation of the stimulation field **655** and target **660**, the user causes generation of an actual stimulation field via the user interface of the CP **130** according to the depicted stimulation field **655** and target **660** as modified by the user in step **520***g*. To generate the actual stimulation field, stimulation field parameters are determined in step **520***h* that, if enacted, will cause the depicted stimulation field **655** to be generated. For instance, the CP **130** includes hardware and/or software to determine which electrodes to enable as cathodes, which electrodes to enable as anodes, and the respective electrical signals (e.g., amplitude, pulse width, pulse shape, pulse frequency, and polarity) to send to each to generate the stimulation field **655** and target **660** as depicted after the user's graphical modifications.

In some implementations, the CP **130** assigns a percentage of the total amplitude to each electrode it determines to enable. For instance, lead **575***a* may have three cathodes assigned with −10%, −80%, and −10%, respectively, while lead **575***b* has four anodes assigned with 10%, 40%, 40%, and 10%, respectively. Thus, the percentages of the cathodes add up to −100% and the percentages of the anodes add up to 100%, for an overall sum of 0%.

Thereafter, in step **520***i*, the user causes the IPG **115** to generate stimulation as determined in step **520***h*. In step **520***i*, the user unlocks the stimulation lock button **635** and enables the stimulation button **640** as described above. When the stimulate button **640** is enabled, a stop button **645** replaces both the stimulation lock button **635** the stimulate button **640** on the display **375** as shown in FIG. **12**H. Additionally, when the stimulate button **640** is enabled, the IPG **115** is instructed to generate stimulation as determined in step **520***h*.

The user is further able to graphically manipulate the stimulation field **655** and target **660** on-the-fly (i.e., while actual stimulation is on-going). Thus, steps **520***g* and **520***h* may be repeated while the IPG **115** is providing stimulation to the patient. Additionally, in some instances, the CP **130** causes generation of a stimulation field (step **520***i*) before steps **520***g* and **520***h*, such that the graphical manipulations occur while the IPG **115** is providing stimulation to the patient.

In some implementations, steps **520***g*-**520***i* are combined with method **510**. That is, in place of steps **520***a*-**520***f*, method **510** is first used to generate a suggested stimulation field **540** and target **545** as shown in FIG. **15**. The suggested stimulation field **540** and target **545** are used in place of the determined and displayed stimulation field **655** and target **660** of step **520***f*. Thereafter, steps **520***g*, **520***h*, and **520***i* are executed. Thus, the user is able to modify the suggested stimulation field **540** and target **545** in step **520***g*; the appropriate stimulation parameters are determined to generate the modified (or unmodified) suggested stimulation field **540** and target **545** in step **520***h*; and the modified (or unmodified) suggested stimulation field and target are generated via the IPG **115** according to the determined stimulation parameters in step **520***i*.

FIG. **17** depicts a step **525** (also referred to as method **525**) for an automated search for an ideal stimulation field based on real-time patient feedback. In step **525***a*, the patient spinal column **560** is depicted on the display **375** of the CP **130**, similar to step **510***a* and **520***a* of methods **510** and **520**, respectively. In step **525***b*, positions of medical leads implanted in the patient are determined. For instance, the user of the CP **130** may input the location of the medical leads as described above with respect to steps **510***b*-**510***d*, and **520***b-d* in methods **510** and **520**, respectively. Additionally, as also described above, the IPG **115** may store the positions of the implanted medical leads. Thus, in step **525***b*, the IPG **115** may communicate the positions of the implanted medical leads to the CP **130**. Images of the leads **575***a* and **575***b* are then overlaid on the spinal column **560** according to the medical lead position data obtained from the user, the IPG **115**, or another source.

In step **525***c*, a set of regions **720** is also overlaid on the spinal column **560** on the display **375**. FIG. **18**A illustrates the display **375** with the spinal column **560**, leads **575***a* and **575***b*, and set of regions **720**. The set of regions **720** may be positioned over an area where the stimulation is generally expected to help alleviate pain. For instance, based on practitioner experience or the method **505**, the CP **130** determines a general area to receive stimulation. Then, the CP **130** overlays the set of regions **720** on the determined general area. The set of regions **720** is depicted in FIG. **18**A as a 3×3 grid of squares. However, in some embodiments, the set of regions **720** includes regions of different sizes, shapes (circles, diamonds, rectangles, hexagons, etc.), and/or combinations thereof.

In step **525***d*, the CP **130** causes the IPG **115** to generate stimulation in each region of the set of regions **720** consecutively. For instance, as shown in FIG. **18**A, the CP **130** causes the IPG **115** to generate stimulation in the upper-left region first, and winds down along the path **730** stimulating one square at a time until the last square of the set of regions **720** is stimulated. FIG. **19**A illustrates the same path for stimulating each region of the set of regions **720**. In FIG. **19**A, a stimulation field **735***a* and target **735***b* is generated in the top, middle region **740** of the set of regions **720**.

As each region of the set of regions **720** is stimulated, the CP **130** receives real-time patient feedback. For instance, the patient **105** indicates via patient feedback device **145** the level of effectiveness of the stimulation of each of the nine regions within the set of regions **720**. The IPG **115** and CP **130** may cooperate such that the stimulation field **735***a* and target **735***b* are generated for a first region of the set of regions **720**, and they remain until the user provides feedback. Once the feedback is received, the CP **130** causes the IPG **115** to generate a stimulation field in the second region. This process continues until each region of the set of regions **720** has been stimulated and each has been associated with user feedback.

In step **525***e*, the CP **130** analyzes the patient feedback of step **525***d* to determine a first subset **750** of the set of regions

720. The first subset 750 includes those regions whose stimulation was most effective in reducing the patient's pain. In FIGS. 18B and 19B, the first subset 750 is highlighted. Determining the first subset 750 may be performed in one or more ways. For instance, the first subset 750 may include the top N regions of the set of regions 720, where N is a number greater than zero and less than the total number of regions within the set of regions 720, or where N is a percentage of the total number of regions within the set of regions 720 (e.g., 25%, which would round to N=2). In some instances, those regions that are below a certain predetermined threshold of effectiveness will not qualify for the first subset 750. Alternatively, any region that is above a predetermined threshold of effectiveness may qualify for the first subset 750.

In step 525*f*, a set of subregions 760 are displayed within the first subset 750, as illustrated in FIGS. 18C and 19C. FIG. 18D depicts a close-up view of the subregions 760 of FIG. 18C. The set of subregions 760 includes a 2×4 grid of squares that occupy the space of the first subset 750. As with the set of regions 720, the set of subregions 760 can include subregions of different sizes, shapes, and combinations thereof.

In step 525*g*, the CP 130 causes the IPG 115 to generate stimulation in each subregion of the set of subregions 760 consecutively. For instance, as shown in FIGS. 18C, 18D, and 19C, the CP 130 causes the IPG 115 to generate stimulation in the upper-left subregion first, and then to stimulate one square at a time winding down the path 770 until the last square of the set of subregions 760 is stimulated. In FIG. 19C, a stimulation field 775 (with field 775*a* and target 775*b*) is being generated in the top, right subregion 780 of the set of subregions 760.

As each subregion of the set of subregions 760 is stimulated, the CP 130 receives real-time patient feedback similar to the stimulation and feedback described in step 525*d* for the set of regions 720. For instance, the patient 105 indicates via patient feedback device 145 the level of effectiveness of the stimulation of each of the eight subregions within the set of subregions 760.

In step 525*h*, the CP 130 analyzes the patient feedback of step 525*g* to determine a second subset 790 of the set of subregions 760. The second subset 790 includes those subregions whose stimulation was most effective in reducing the patient's pain, similar to the first subset 750. In FIG. 19D, the second subset 790 is highlighted.

In step 525*i*, the CP 130 determines a stimulation field 800*a* and target 800*b* that focuses on the second subset 790. Step 525*i* is similar to step 520*g* in that a general graphical outline of a stimulation field is known, and stimulation parameters to cause actual stimulation according to the outline are determined by the CP 130. The CP 130 then provides the stimulation parameters to the IPG 115, which stores them and generates the desired stimulation via the implanted medical leads 110.

The methods 505, 510, 520, and 525 reduce pain in patients through customized stimulation and reduce the time needed for programming of the IPG 115. Additionally, as particular areas are identified to receive targeted stimulation, rather than broad stimulation areas, the stimulation is more efficiently implemented. More efficient stimulation reduces power consumption, which increases the life of batteries within the IPG 115.

Thus, the invention provides, among other things, useful and systems and methods for providing electrical stimulation to a neural tissue of a patient. Various features and advantages of the invention are set forth in the following claims.

What is claimed is:

1. An automated search method to identify a location for electrical stimulation to treat a patient with a stimulation system, the stimulation system comprising an electrical stimulation generator, a medical lead implanted in the patient and coupled to the electrical stimulation generator, a programmer with a display screen, and a feedback device configured to communicate with the programmer, the method comprising:
   - displaying an image of a spinal column on the display screen of the programmer;
   - displaying a portion representing the medical lead on the image of the spinal column;
   - displaying a first plurality of regions on the image of the spinal column with respect to the portion representing the medical lead, each of the first plurality of regions specifying a respective location for targeting of electrical stimulation within the patient;
   - initiating electrical stimulation with the electrical stimulation generator and the medical lead according to the first plurality of regions;
   - receiving feedback indicating the effectiveness of the electrical stimulation to the first plurality of regions;
   - displaying a second plurality of regions on the image of the spinal column with respect to the portion representing the medical lead, the second plurality of regions including subregions on the image within one of the first plurality of regions, wherein the second plurality of regions is displayed based on the feedback from the patient, and wherein each of the second plurality of regions specify a second respective location for targeting of electrical stimulation within the patient;
   - initiating electrical stimulation with the electrical stimulation generator and the medical lead according to the second plurality of regions; and
   - receiving additional feedback indicating the effectiveness of the electrical stimulation to the second plurality of regions.

2. The automated search method of claim 1, further comprising identifying a subset of the second plurality of regions for targeted electrical stimulation based on the additional feedback from the patient.

3. The automated search method of claim 1, wherein each region of the first plurality of regions is a quadrilateral.

4. The automated search method of claim 3, wherein the first plurality of regions form a grid.

5. The automated search method of claim 1, wherein each region of the first plurality of regions shares a boundary with another region of the first plurality of regions.

6. The automated search method of claim 1, wherein the initiating the electrical stimulation according to the first plurality of regions includes initiating electrical stimulation to a first region, then initiating electrical stimulation to a second region adjacent to the first region, and then initiating electrical stimulation to a third region adjacent to the second region.

7. The automated search method of claim 1, further comprising, driving, with the electrical stimulation generator, the medical lead to provide targeted electrical stimulation to the second plurality of regions.

8. The automated search method of claim 1, further comprising, displaying, on the display screen, an initial stimulation field overlaid on the second plurality of regions, wherein the initial stimulation field includes an initial boundary.

9. The automated search method of claim 8, further comprising,
   - receiving graphical manipulations of the initial boundary to define an altered stimulation field, wherein the graphi-

cal manipulations at least one of move and alter the shape of the initial boundary;

determining stimulation parameters to drive the medical lead to generate the altered stimulation field; and

driving, with the electrical stimulation generator, the medical lead according to the determined stimulation parameters.

10. The automated search method of claim **8**, further comprising,

receiving, by the programmer, manual adjustments to stimulation parameters; and

driving, with the electrical stimulation generator, the medical lead according to the stimulation parameters as manually adjusted.

11. A programmer for programming an electrical stimulation generator that provides electrical stimulation to treat a patient via a medical lead, the programmer comprising:

a first interface for communicating with the electrical stimulation generator;

a display screen for displaying images;

a second interface for receiving feedback; and

programming means for

causing the display screen to display an image of a spinal column and a position of a portion of the medical lead relative to the spinal column,

causing the display screen to display a first plurality of regions on the image of the spinal column with respect to the position of the medical lead, each of the first plurality of regions specifying a respective location for targeting of electrical stimulation within the patient;

causing the electrical stimulation generator to drive the medical lead according to the first plurality of regions;

receiving feedback via the second interface indicating the effectiveness of the electrical stimulation to the first plurality of regions;

causing the display screen to display a second plurality of regions on the image of the spinal column with respect to the position of the medical lead, the second plurality of regions including subregions on the image within one of the first plurality of regions, wherein the second plurality of regions is displayed based on the feedback, and wherein each of the second plurality of regions specify a second respective location for targeting of electrical stimulation within the patient;

causing the electrical stimulation generator to drive the medical lead according to the second plurality of regions; and

receiving feedback via the user interface indicating the effectiveness of the electrical stimulation to the second plurality of regions.

12. The stimulation system of claim **11**, wherein the programming means further identifies a subset of the second plurality of regions for targeted electrical stimulation based on the additional patient feedback.

13. The stimulation system of claim **11**, wherein each region of the first plurality of regions is a quadrilateral.

14. The stimulation system of claim **13**, wherein the first plurality of regions form a grid.

15. The stimulation system of claim **11**, wherein each region of the first plurality of regions shares a boundary with another region of the first plurality of regions.

16. The stimulation system of claim **11**, wherein causing the electrical stimulation generator to drive the medical lead according to the first plurality of regions includes causing the medical lead to provide electrical stimulation to a first region, then provide electrical stimulation to a second region adjacent to the first region, and then provide electrical stimulation to a third region adjacent to the second region.

17. The stimulation system of claim **11**, wherein the programming means further causes the display screen to display an initial stimulation field overlaid on the second plurality of regions, wherein the initial stimulation field includes an initial boundary.

18. The stimulation system of claim **17**, wherein the programming means further receives graphical manipulations of the initial boundary to define an altered stimulation field, determines stimulation parameters to drive the medical lead to generate the altered stimulation field, and causes the electrical stimulation generator to drive the medical lead according to the determined stimulation parameters.

19. The stimulation system of claim **11**, wherein the programming means further receives manual adjustments to stimulation parameters and causes the electrical stimulation generator to drive the medical lead according to the stimulation parameters as manually adjusted.

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